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Euliano et al.

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(54) **WETNESS SENSORS, WETNESS MONITORING SYSTEM, AND RELATED METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 467 days.

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Related U.S. Application Data

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(60) Provisional application No. 61/509,774, filed on Jul. 20, 2011, provisional application No. 61/512,071, filed on Jul. 27, 2011.

(51) **Int. Cl.**

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G01N 27/12	(2006.01)
G06F 19/00	(2018.01)

(52) **U.S. Cl.**

CPC ***A61F 13/42*** (2013.01); ***G01N 27/121*** (2013.01); ***G06F 19/00*** (2013.01); *A61F 2013/424* (2013.01)

(58) **Field of Classification Search**

CPC A61F 13/42; A61F 2013/424
See application file for complete search history.

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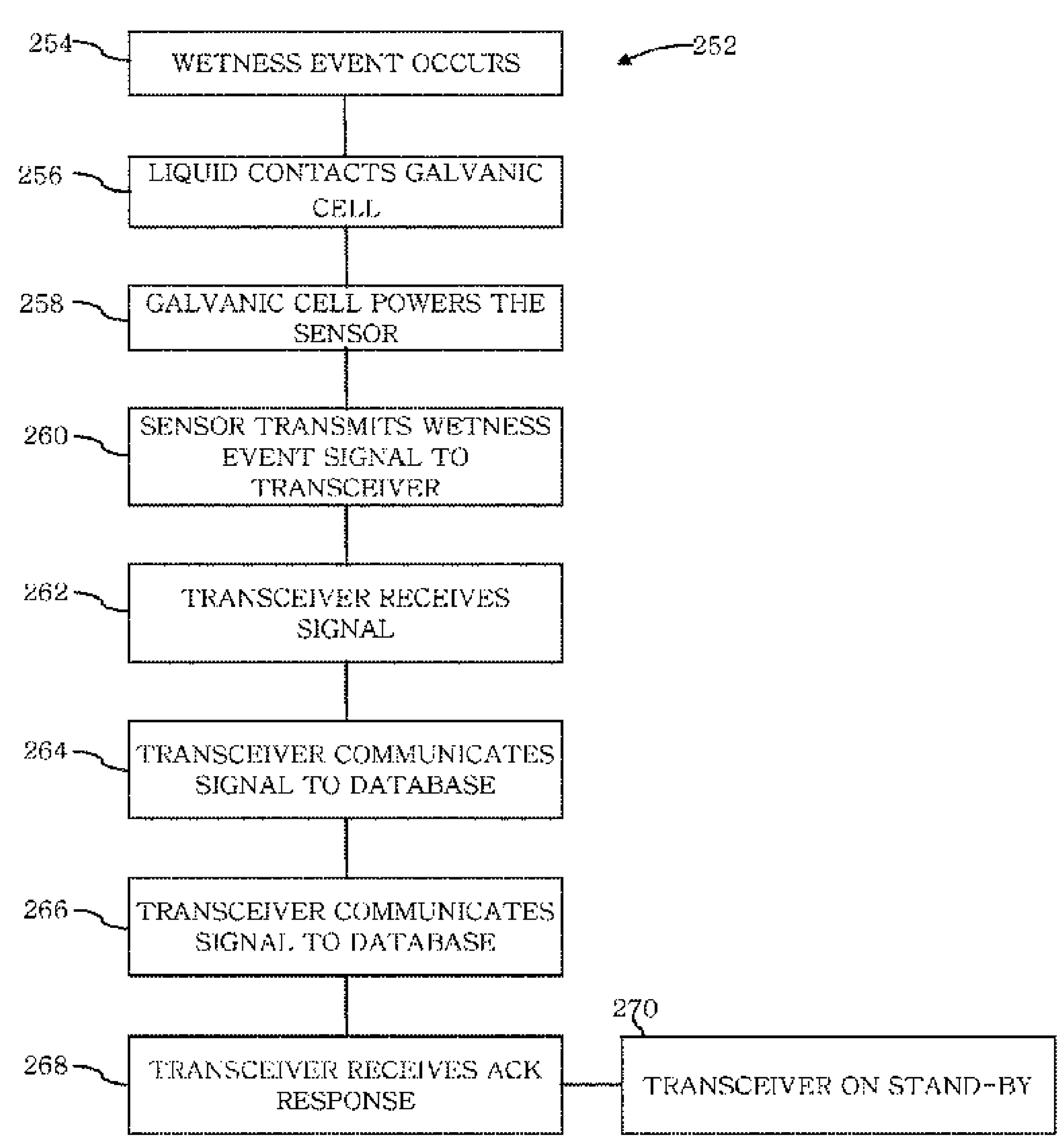
(74) *Attorney, Agent, or Firm* — Bass, Berry & Sims, PLC

(57) **ABSTRACT**

An aspect of the invention is a liquid sensor having a galvanically energizable power source capable of activating a remotely detectable signal in response to liquid. In a preferred embodiment, a liquid sensor includes a plurality of electrodes, a circuit, and a transmitter thereon. The electrodes are coupled to generate electrical power when in contact with liquid. The circuit is electrically connected to the electrodes so as to be activated by the electrical power, detect an electrical parameter of the electrical power, and generate a plurality of data packets indicating a degree of wetness corresponding to the detected electrical parameter. The transmitter is electrically coupled to the circuit to receive the plurality of data packets and transmit representations of the plurality of data packets as electromagnetic signals. Other aspects include a liquid absorbent wetness sensor and a computer-based wetness monitoring system, and method of detecting liquid.

8 Claims, 14 Drawing Sheets



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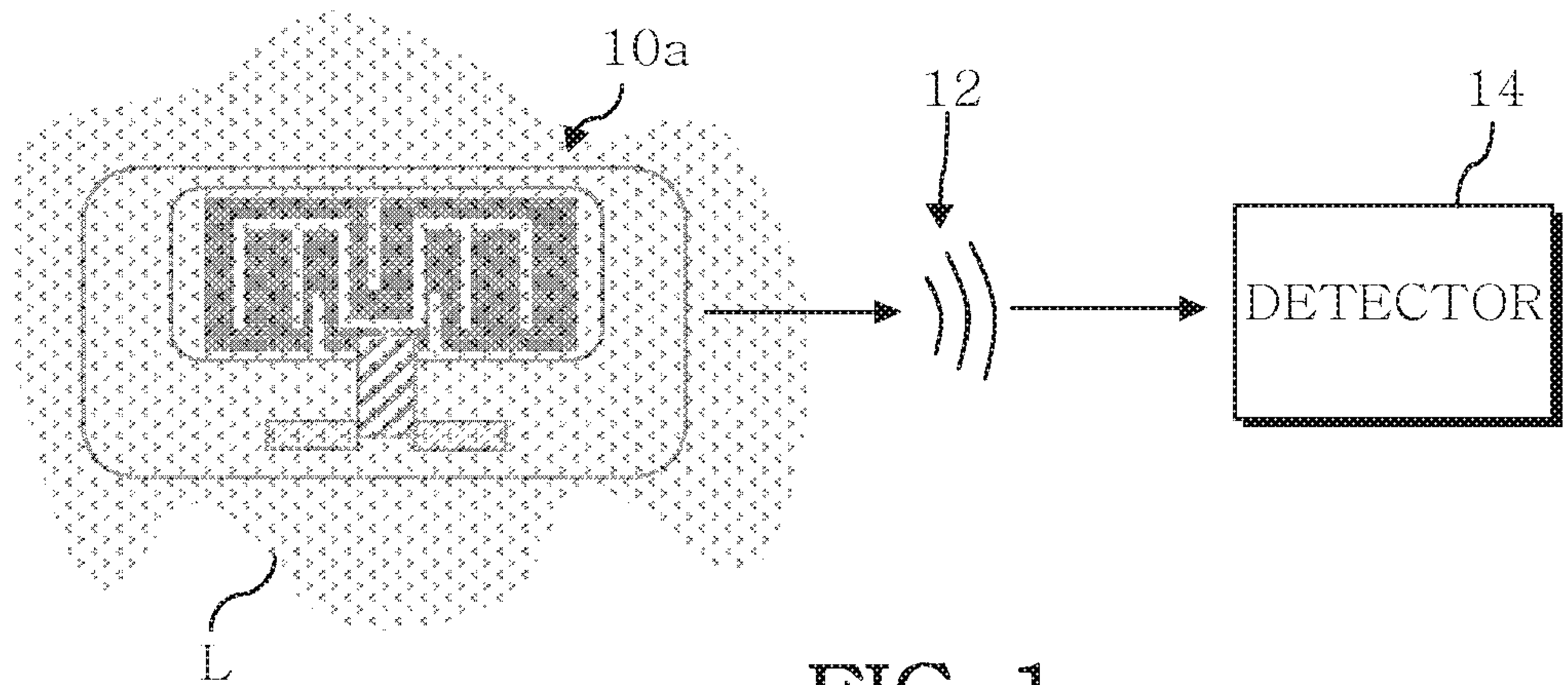

FIG. 1

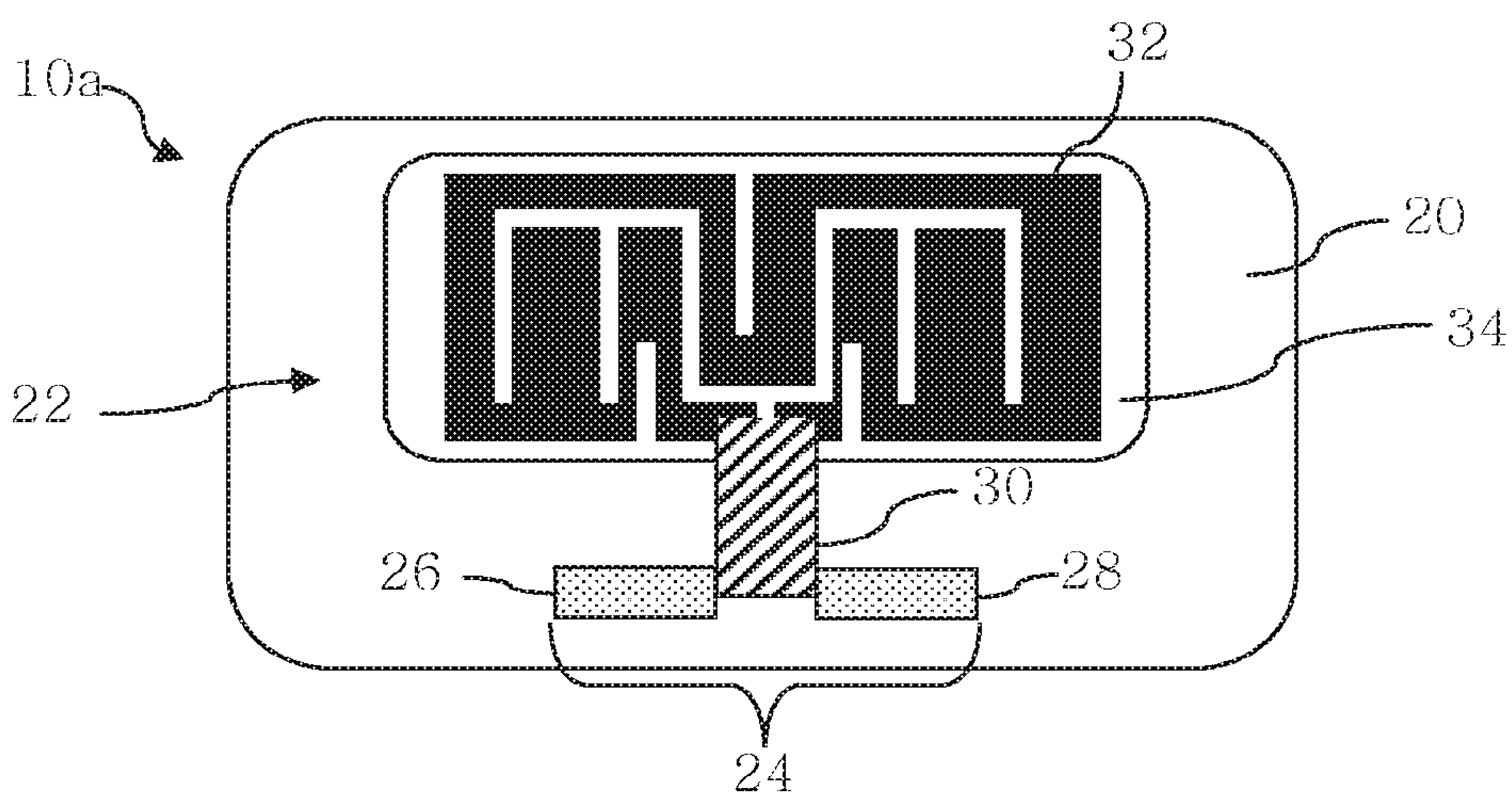

FIG. 2

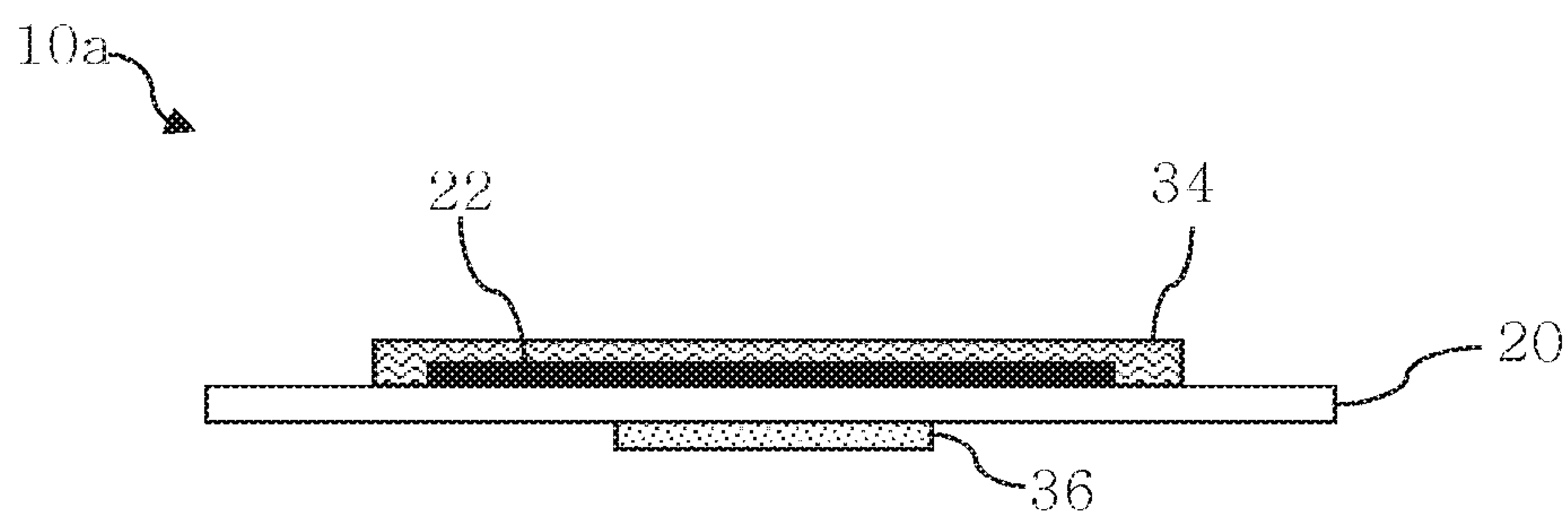

FIG. 3

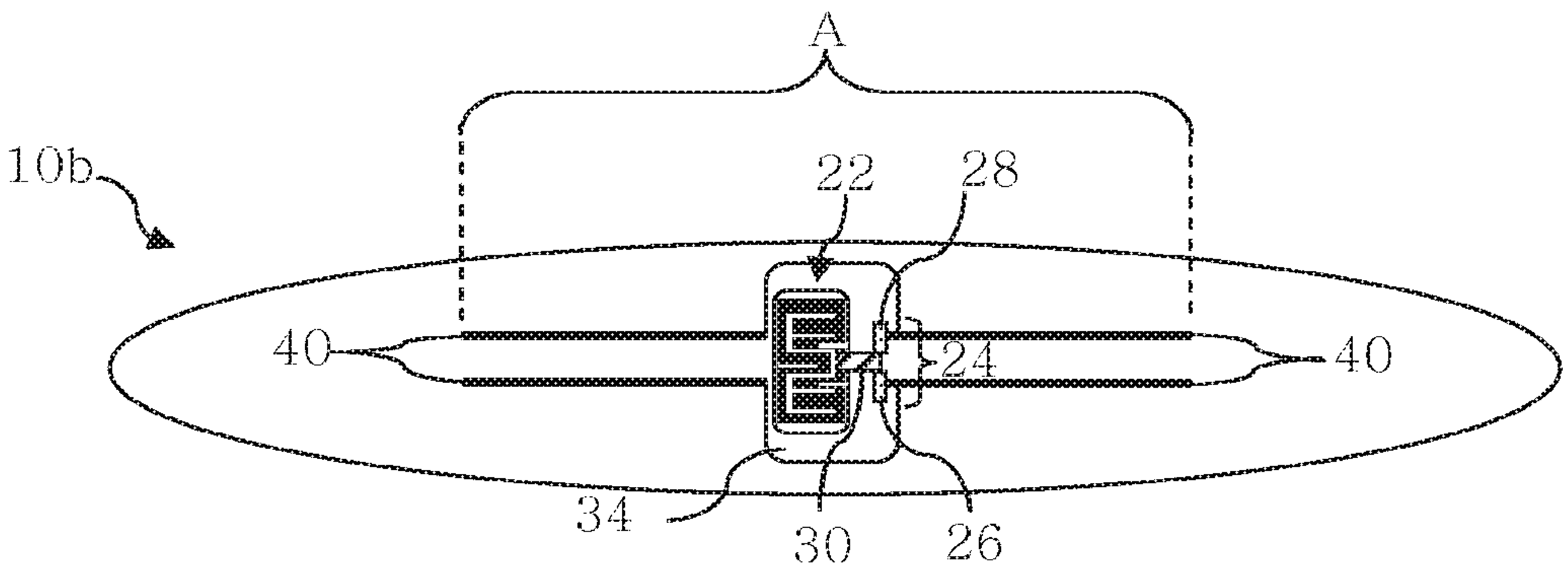

FIG. 4

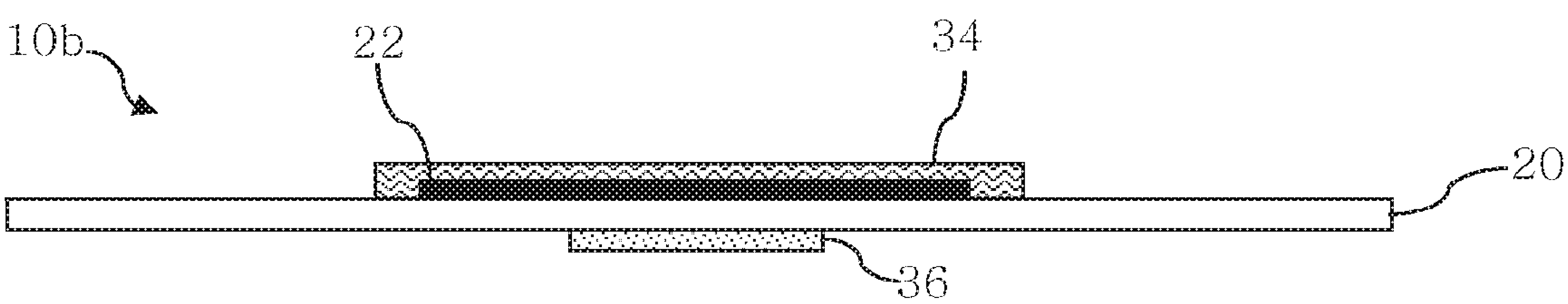

FIG. 5

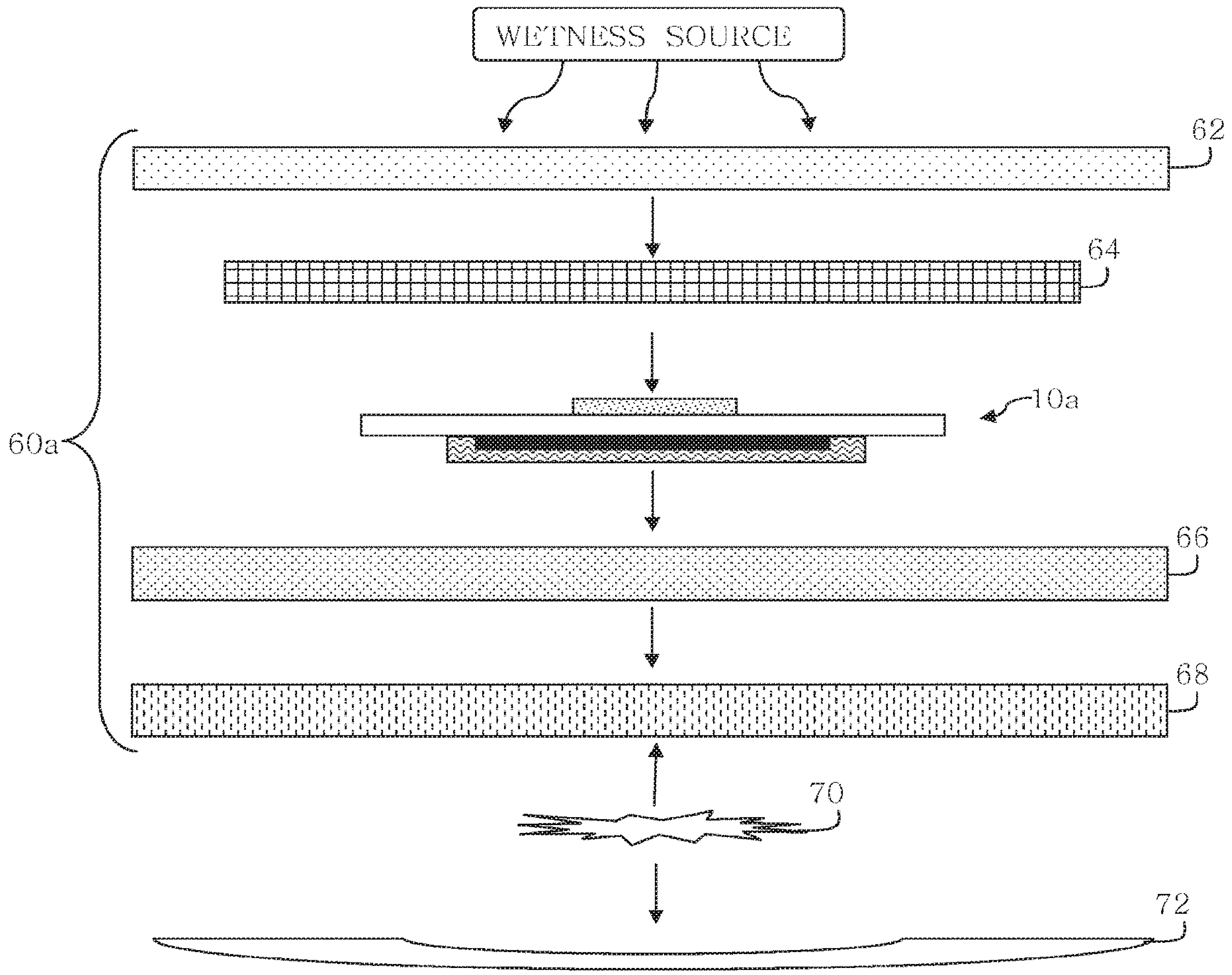

FIG. 6

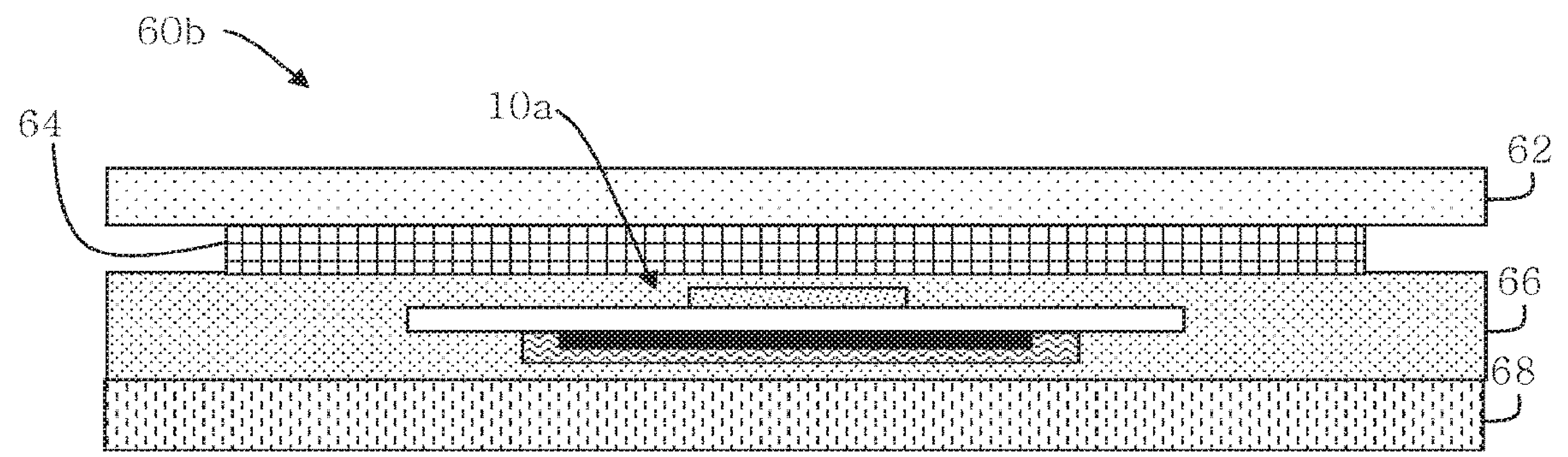

FIG. 7

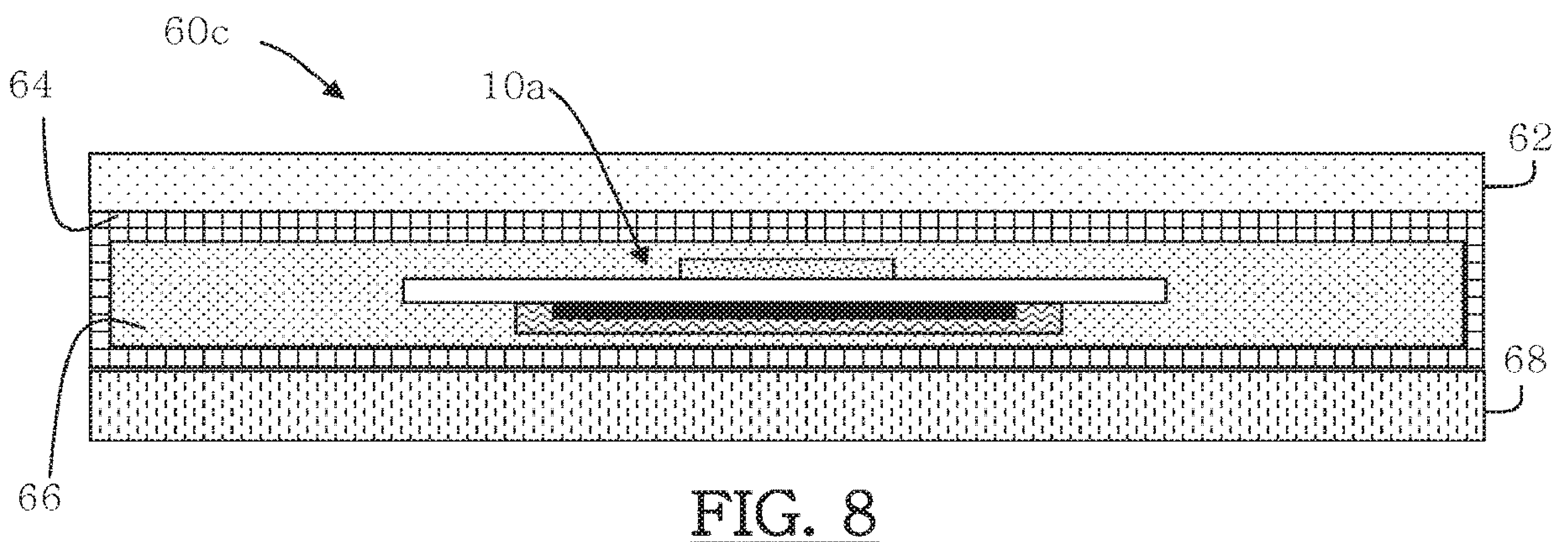

FIG. 8

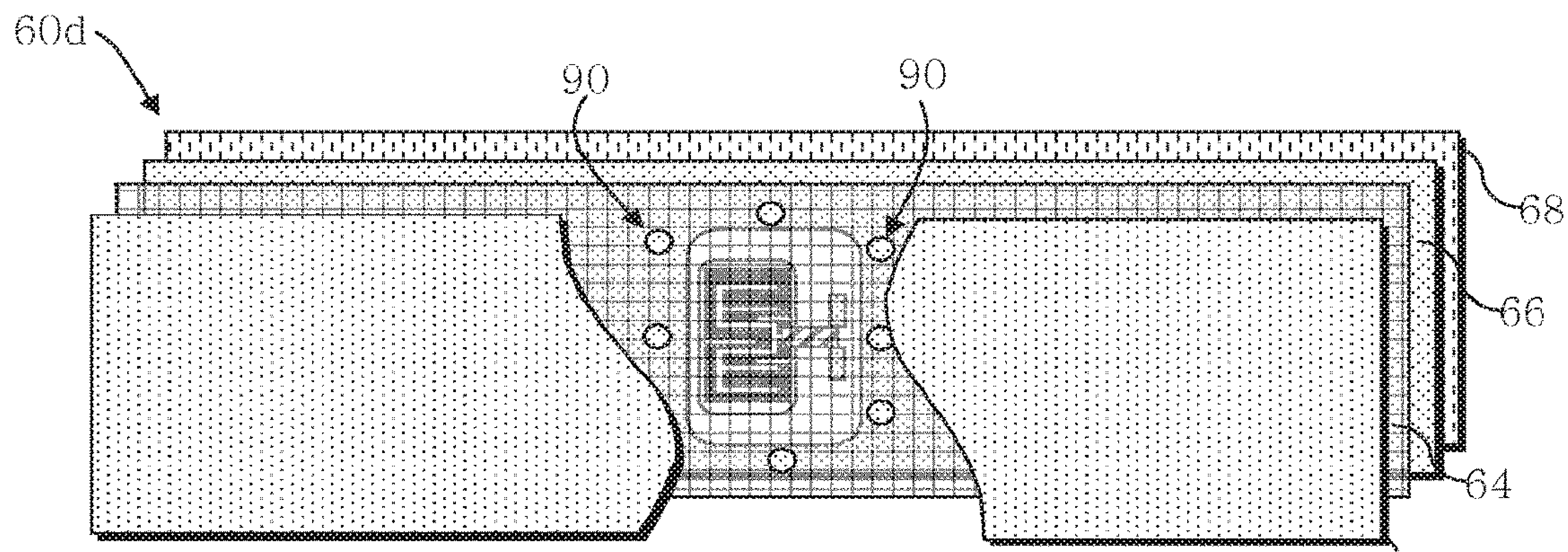

FIG. 9

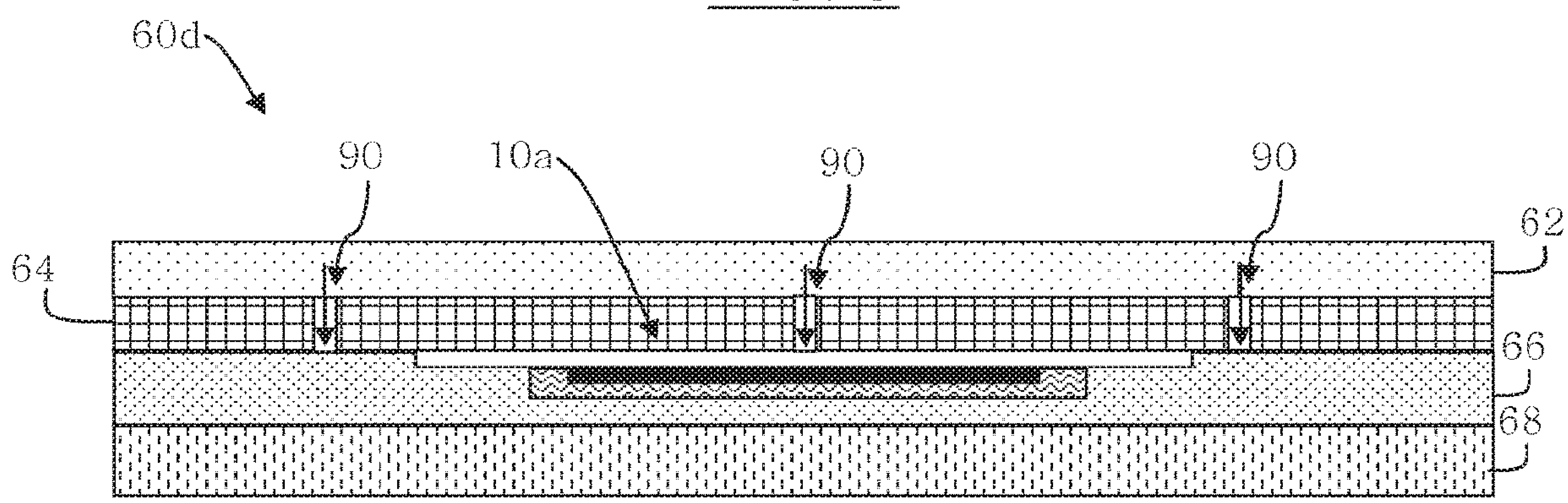

FIG. 10

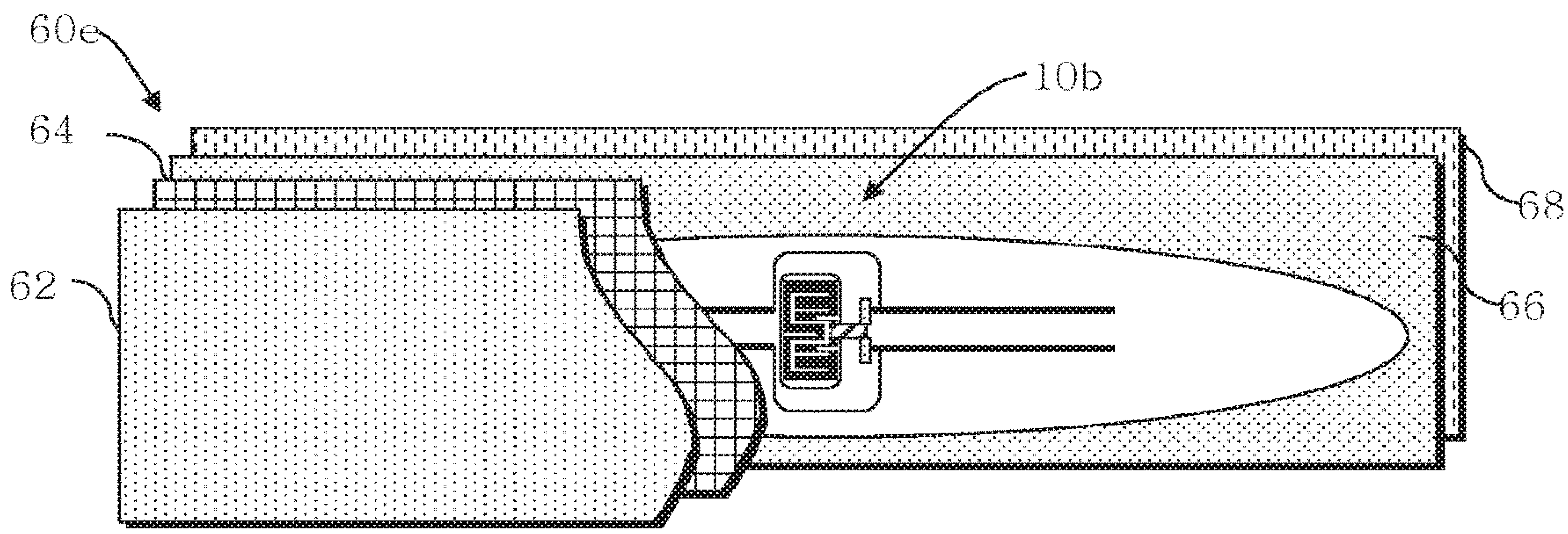

FIG. 11

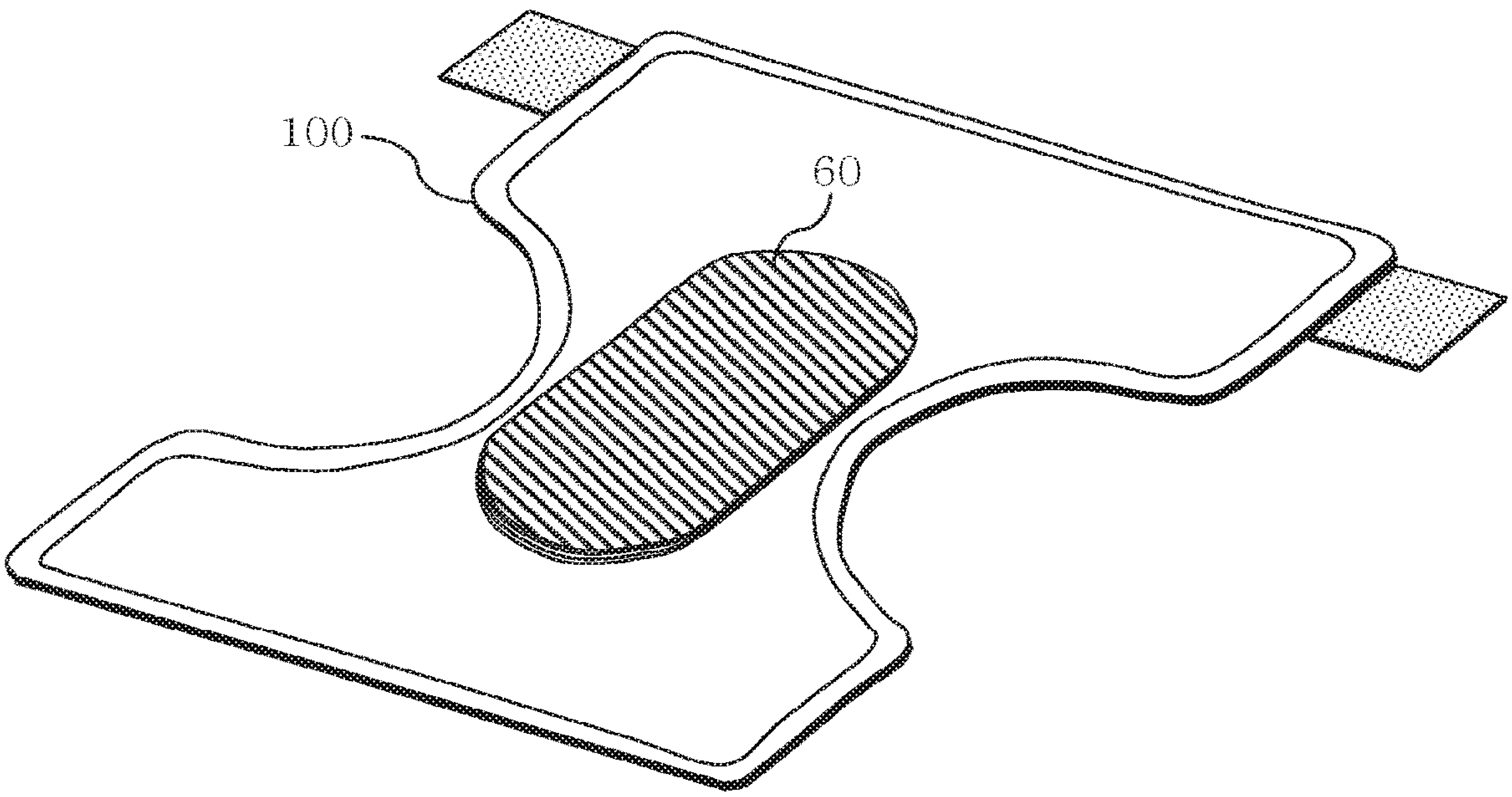

FIG. 12

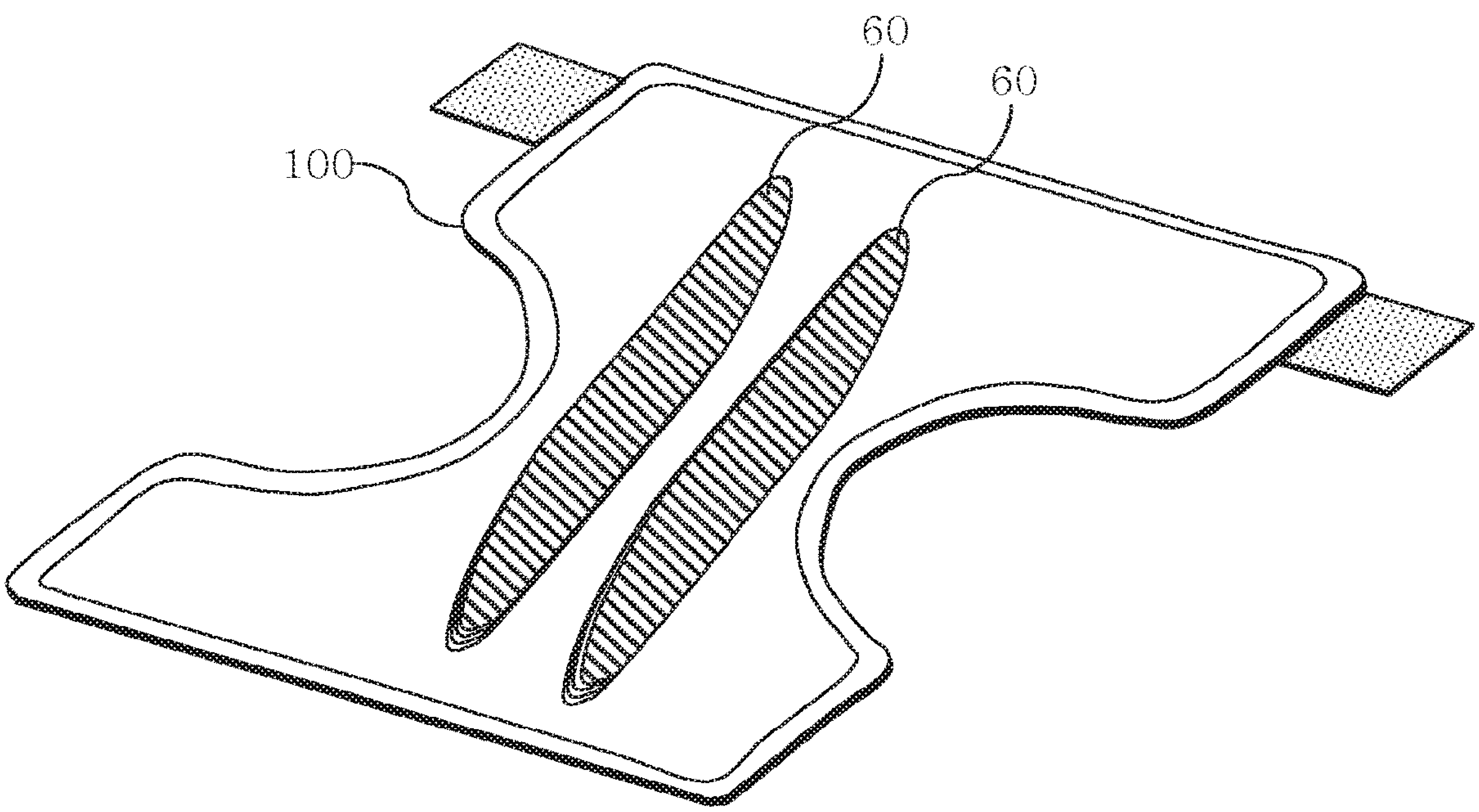

FIG. 13

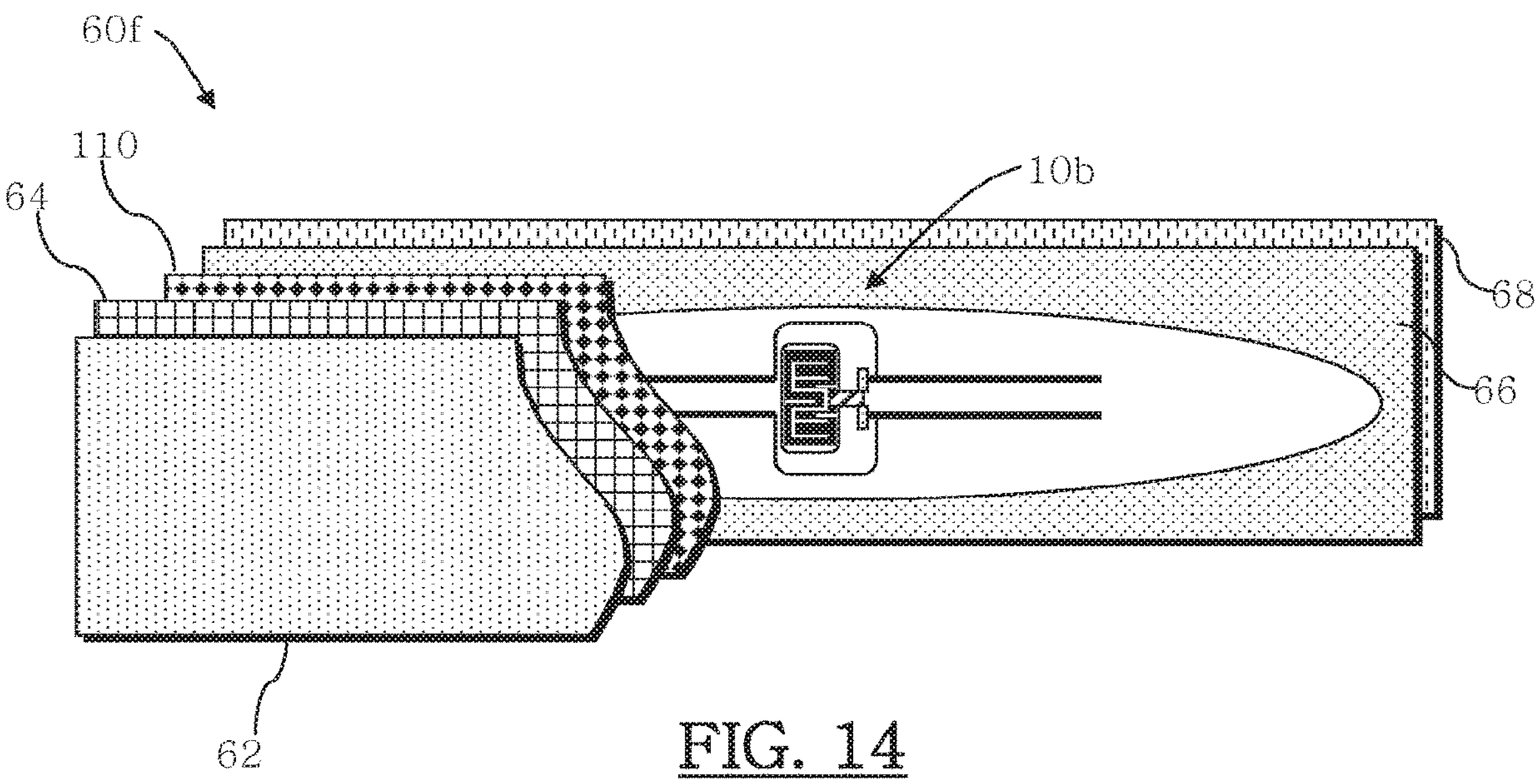

FIG. 14

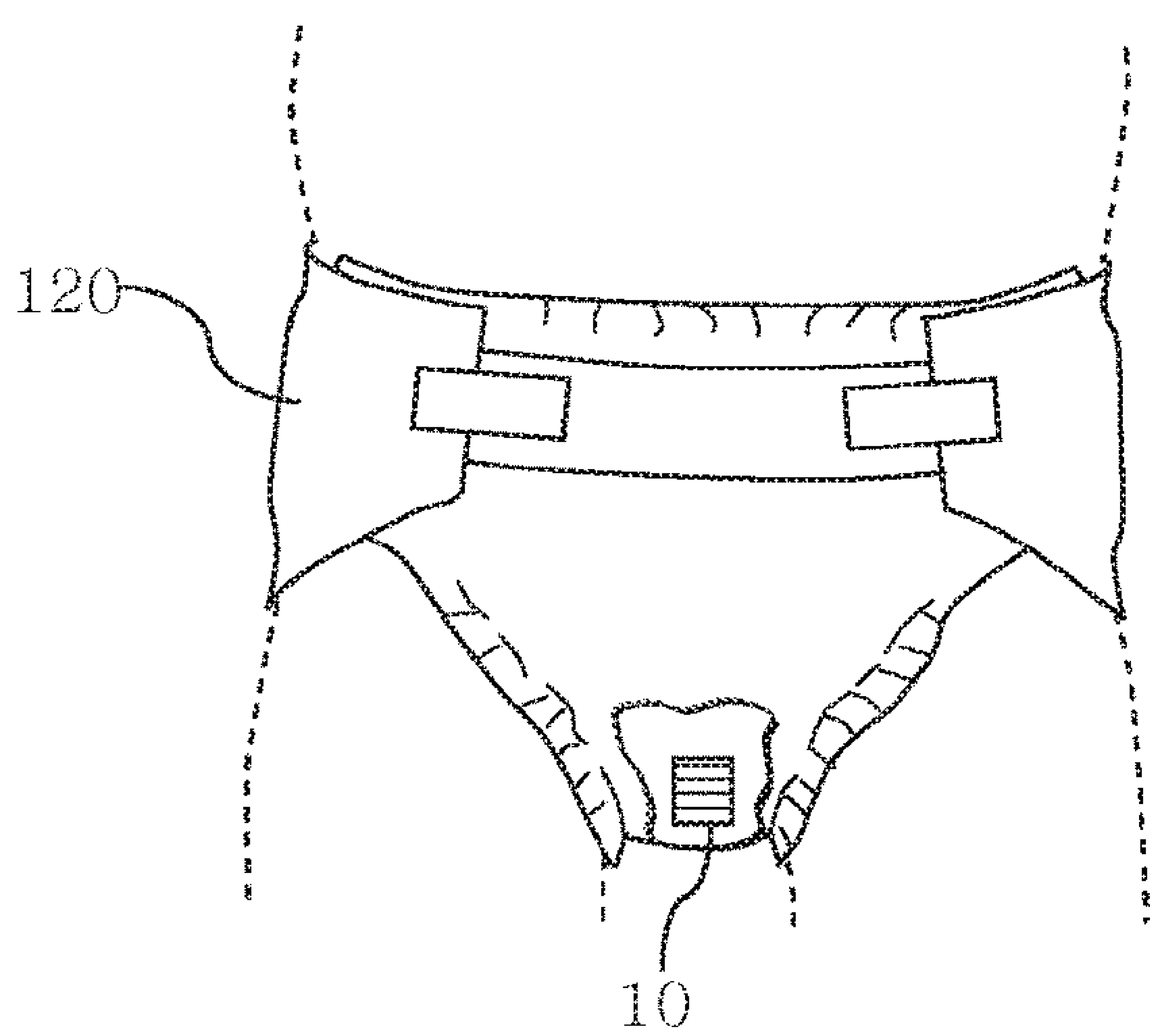

FIG. 15

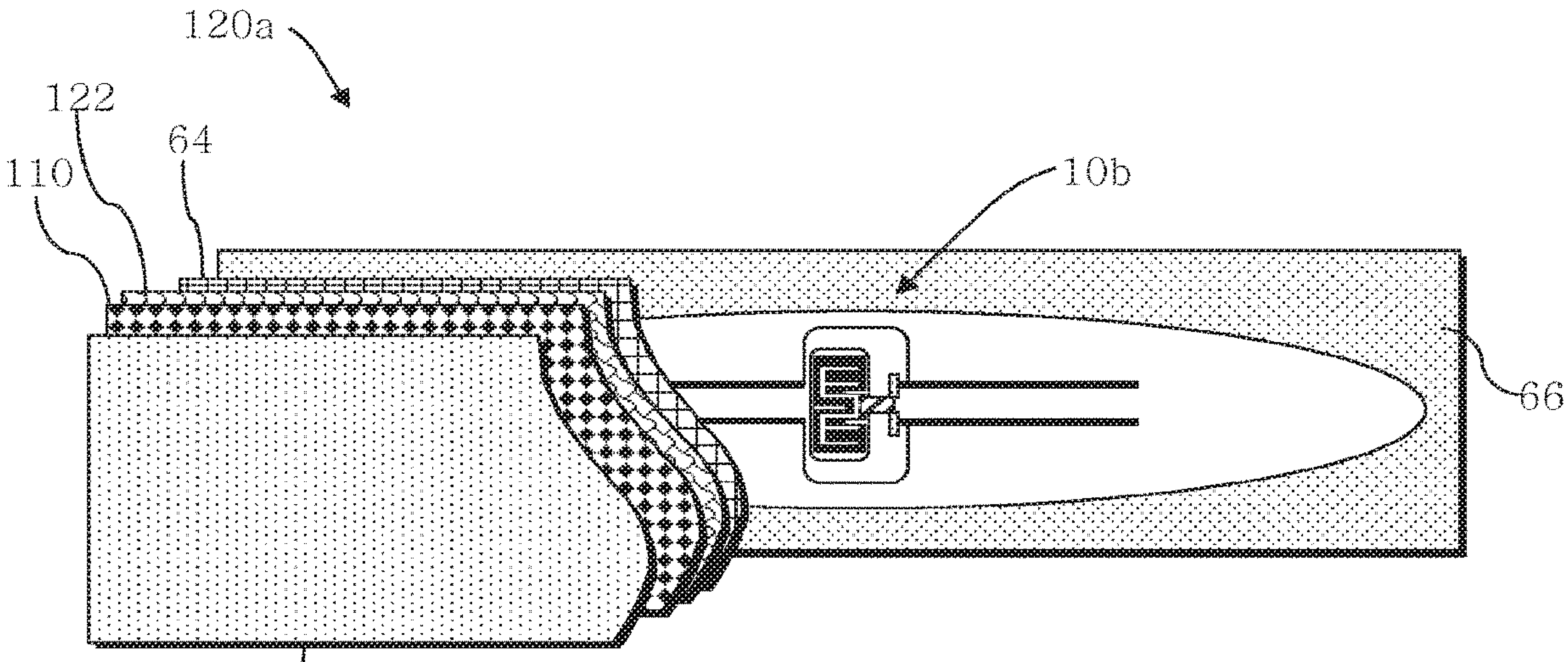

FIG. 16

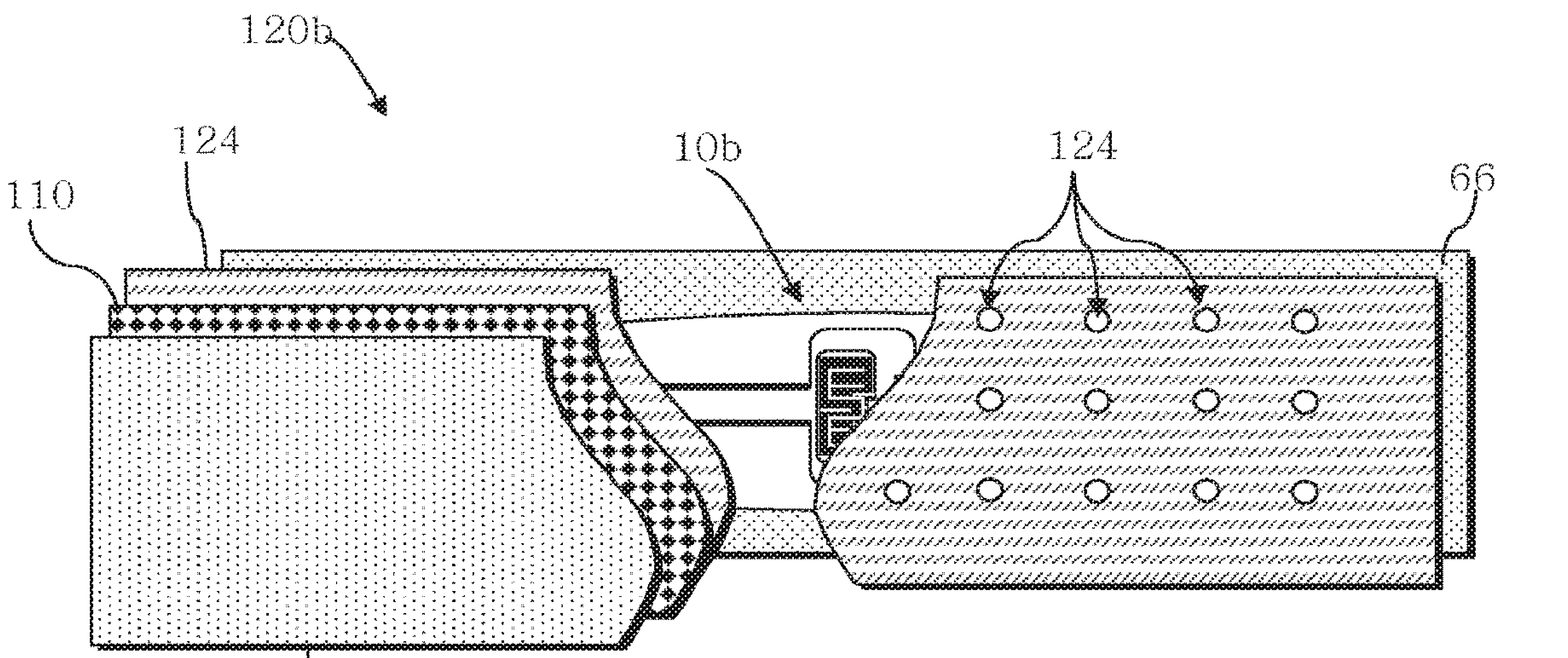

FIG. 17

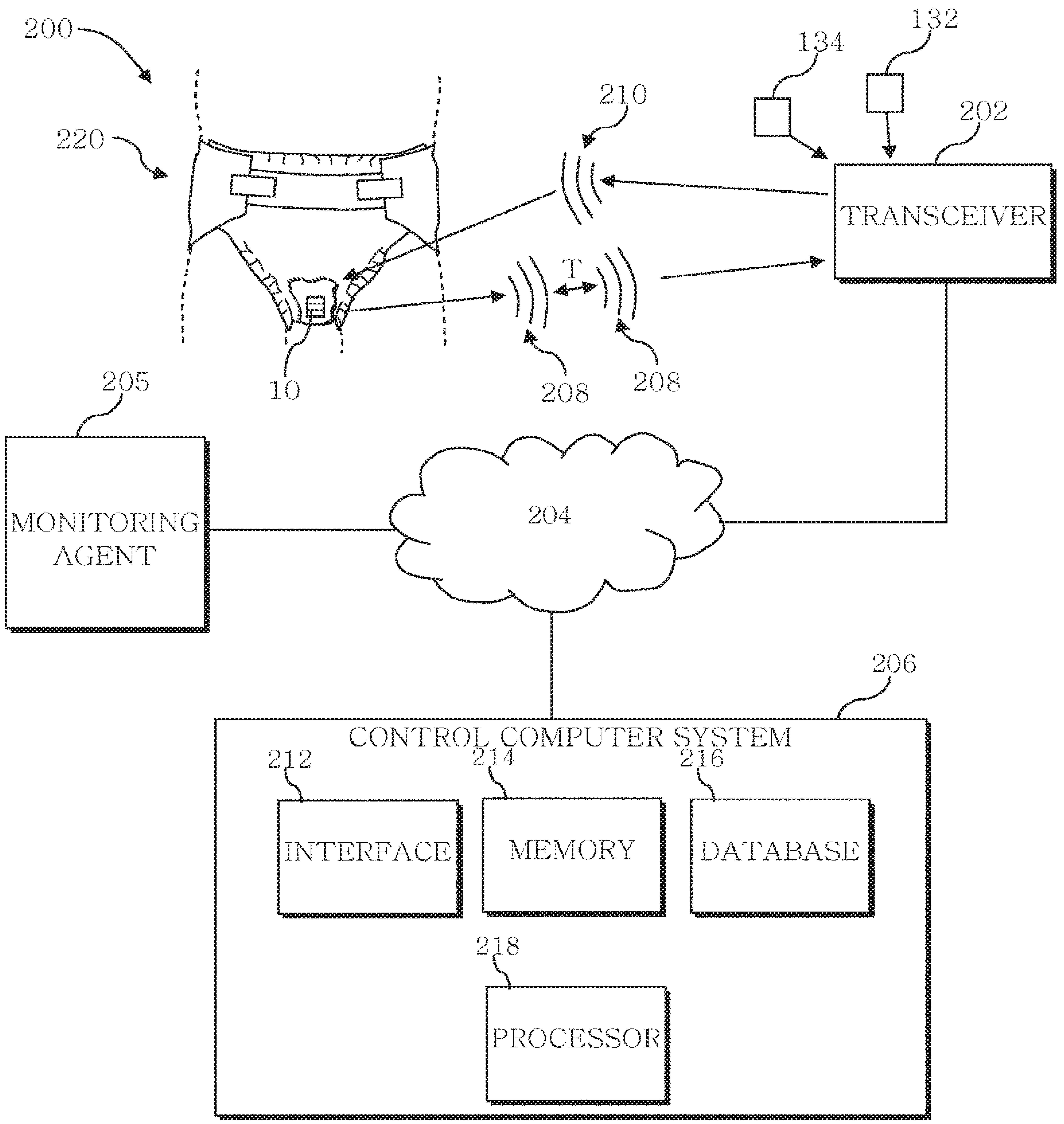
200
220
210
134
132
202
TRANSCEIVER
T
10
208
208
205
MONITORING AGENT
204
206
CONTROL COMPUTER SYSTEM
212
214
216
INTERFACE
MEMORY
DATABASE
218
PROCESSOR

FIG. 18

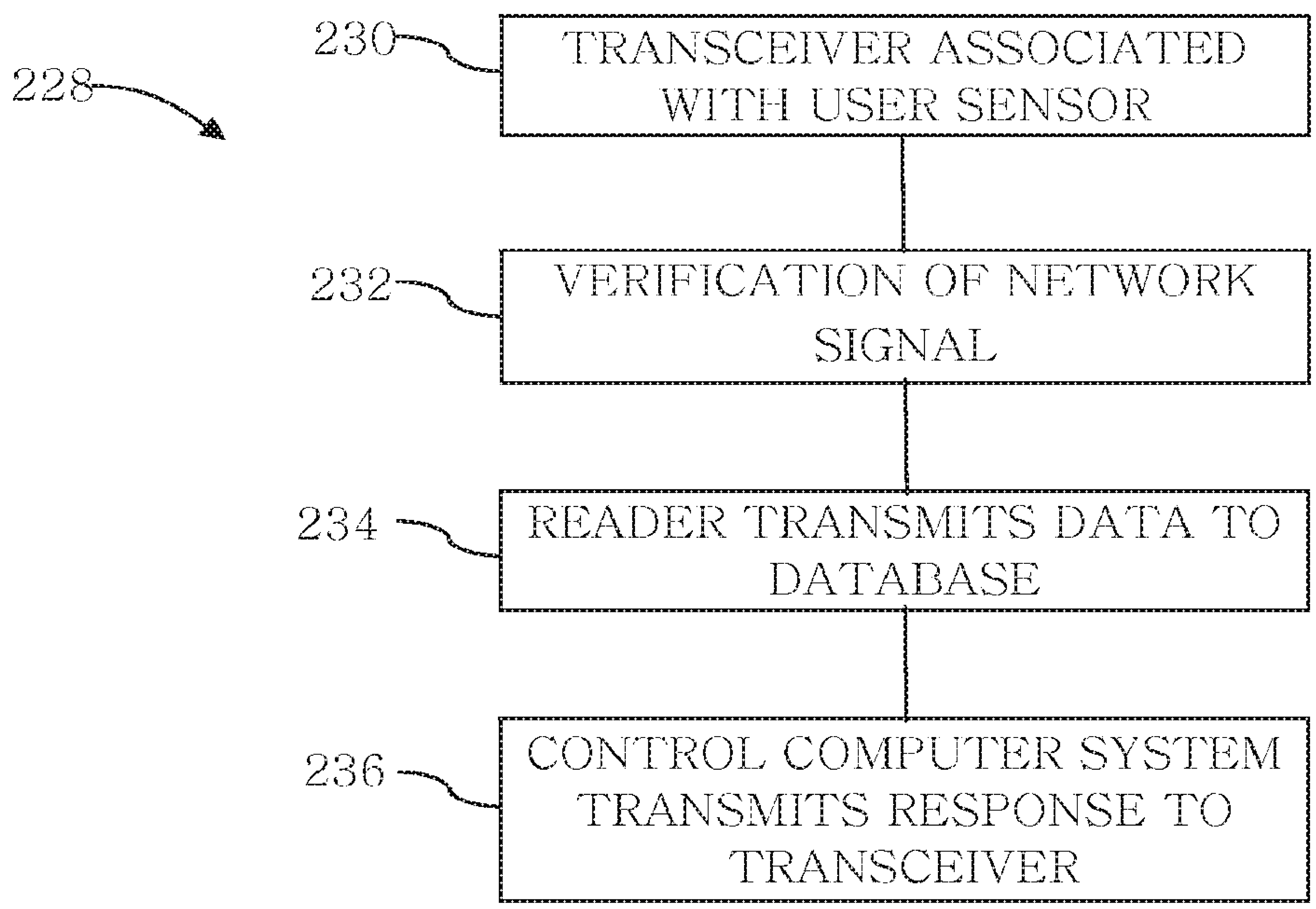
228
230
TRANSCEIVER ASSOCIATED WITH USER SENSOR
232
VERIFICATION OF NETWORK SIGNAL
234
READER TRANSMITS DATA TO DATABASE
236
CONTROL COMPUTER SYSTEM TRANSMITS RESPONSE TO TRANSCEIVER

FIG. 19

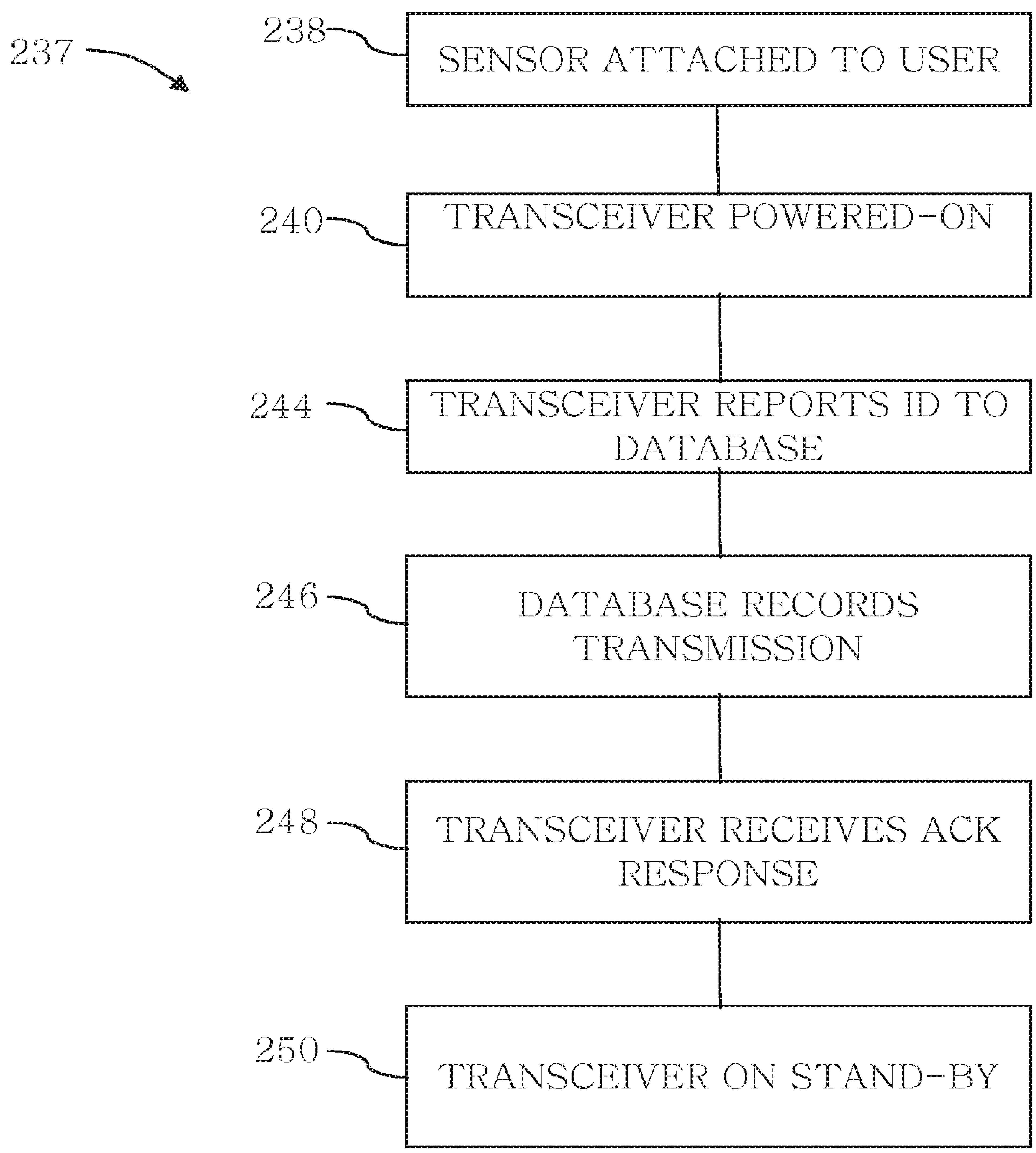
237
238
SENSOR ATTACHED TO USER
240
TRANSCEIVER POWERED-ON
244
TRANSCEIVER REPORTS ID TO DATABASE
246
DATABASE RECORDS TRANSMISSION
248
TRANSCEIVER RECEIVES ACK RESPONSE
250
TRANSCEIVER ON STAND-BY

FIG. 20

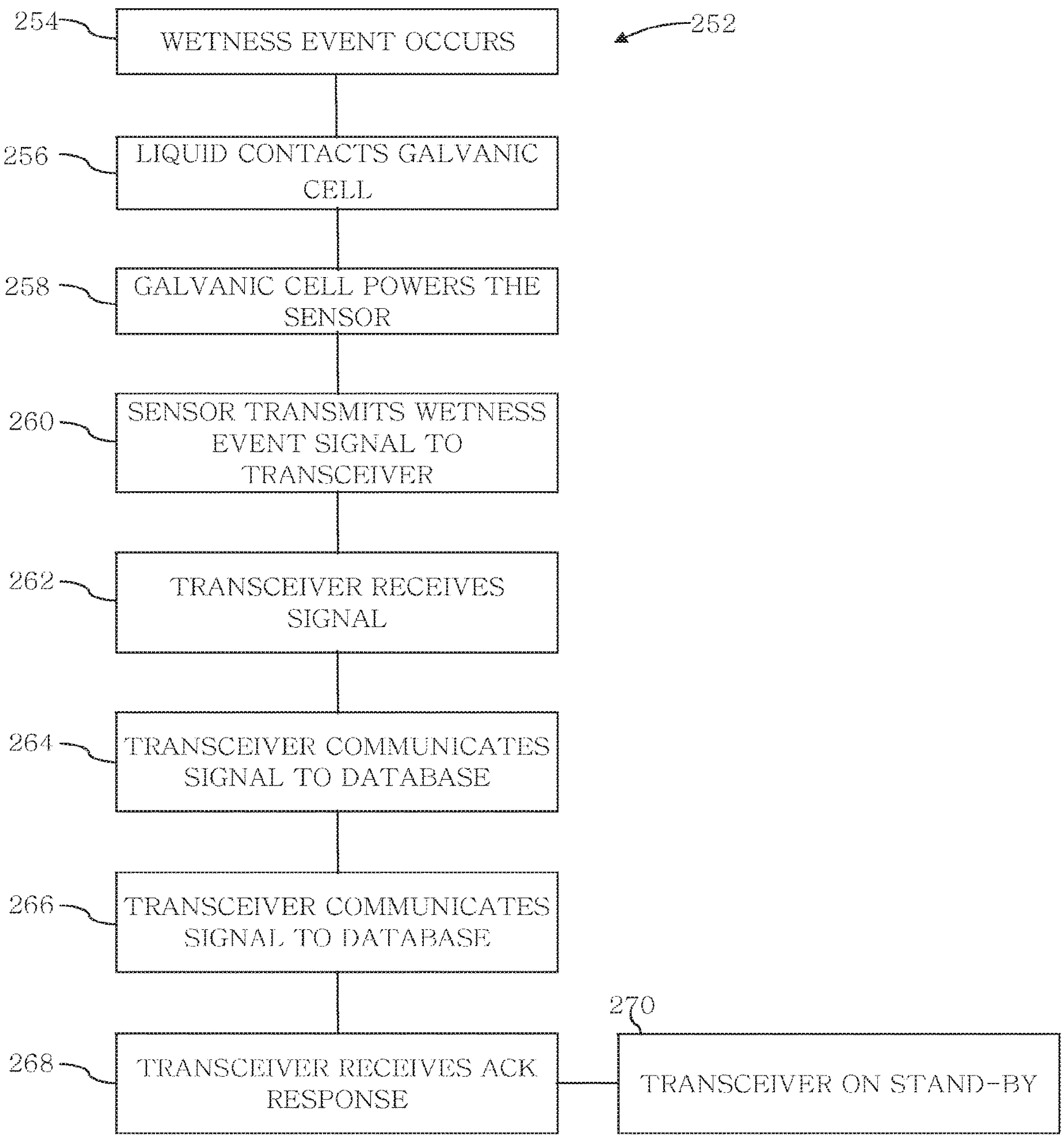
252
254
WETNESS EVENT OCCURS
256
LIQUID CONTACTS GALVANIC CELL
258
GALVANIC CELL POWERS THE SENSOR
260
SENSOR TRANSMITS WETNESS EVENT SIGNAL TO TRANSCEIVER
262
TRANSCEIVER RECEIVES SIGNAL
264
TRANSCEIVER COMMUNICATES SIGNAL TO DATABASE
266
TRANSCEIVER COMMUNICATES SIGNAL TO DATABASE
268
TRANSCEIVER RECEIVES ACK RESPONSE
270
TRANSCEIVER ON STAND-BY

FIG. 21

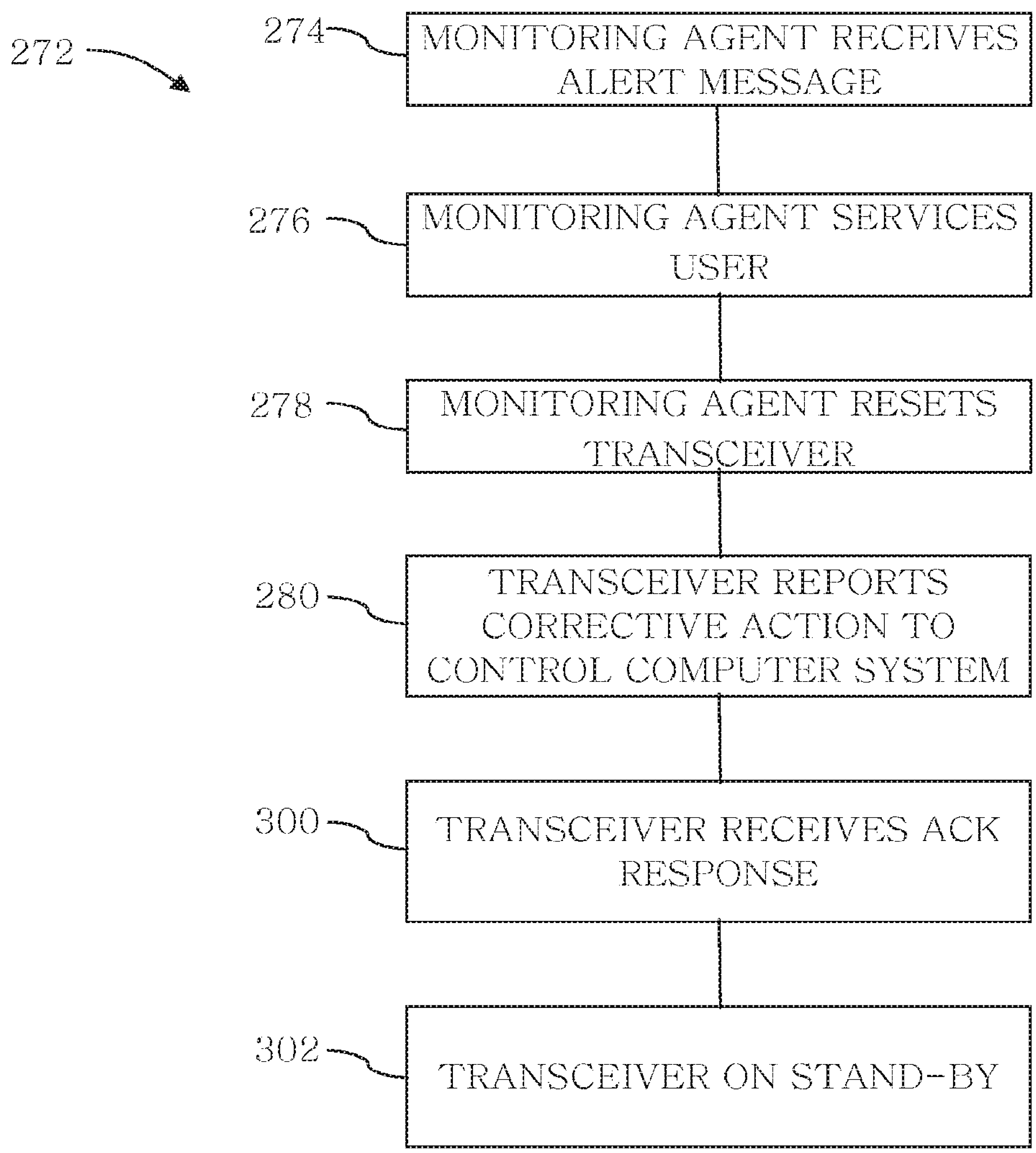
272
274
MONITORING AGENT RECEIVES ALERT MESSAGE
276
MONITORING AGENT SERVICES USER
278
MONITORING AGENT RESETS TRANSCEIVER
280
TRANSCEIVER REPORTS CORRECTIVE ACTION TO CONTROL COMPUTER SYSTEM
300
TRANSCEIVER RECEIVES ACK RESPONSE
302
TRANSCEIVER ON STAND-BY

FIG. 22

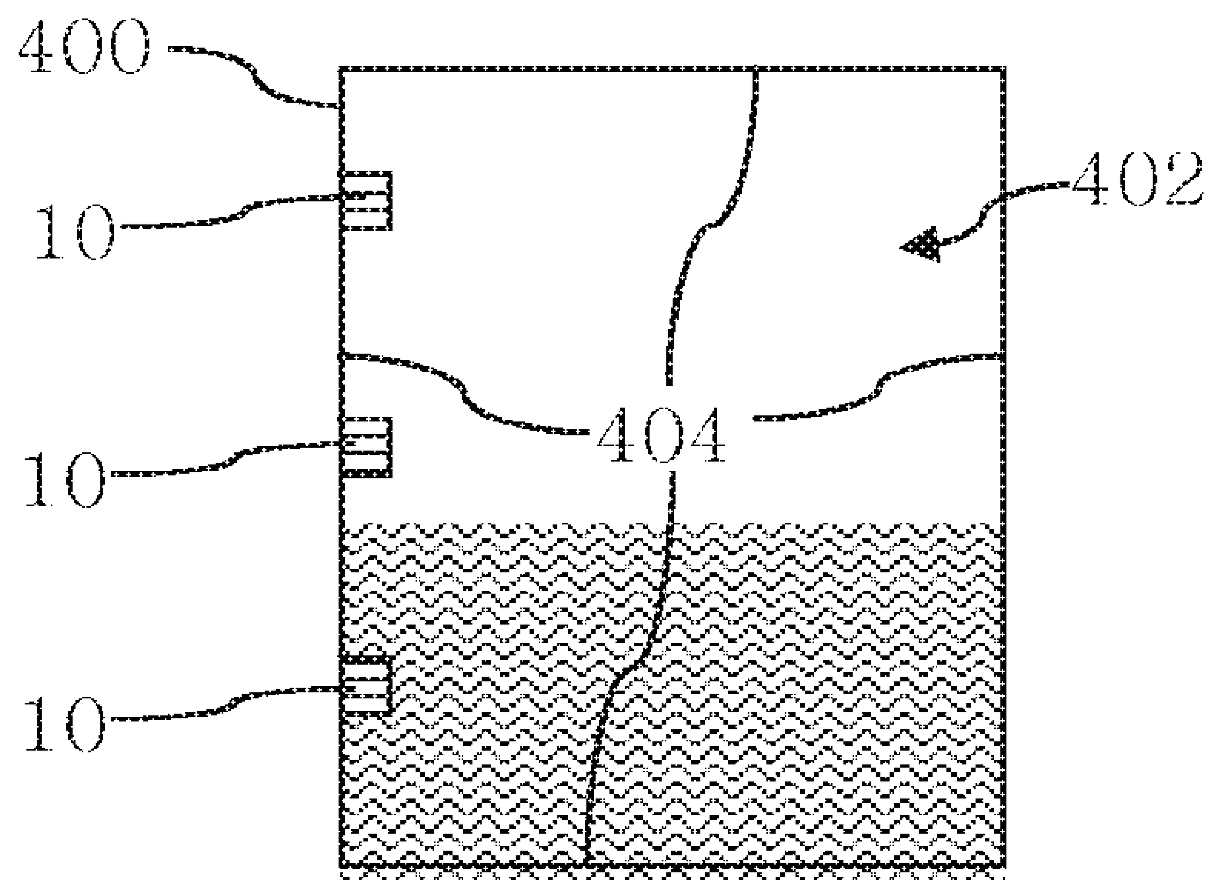

FIG. 23

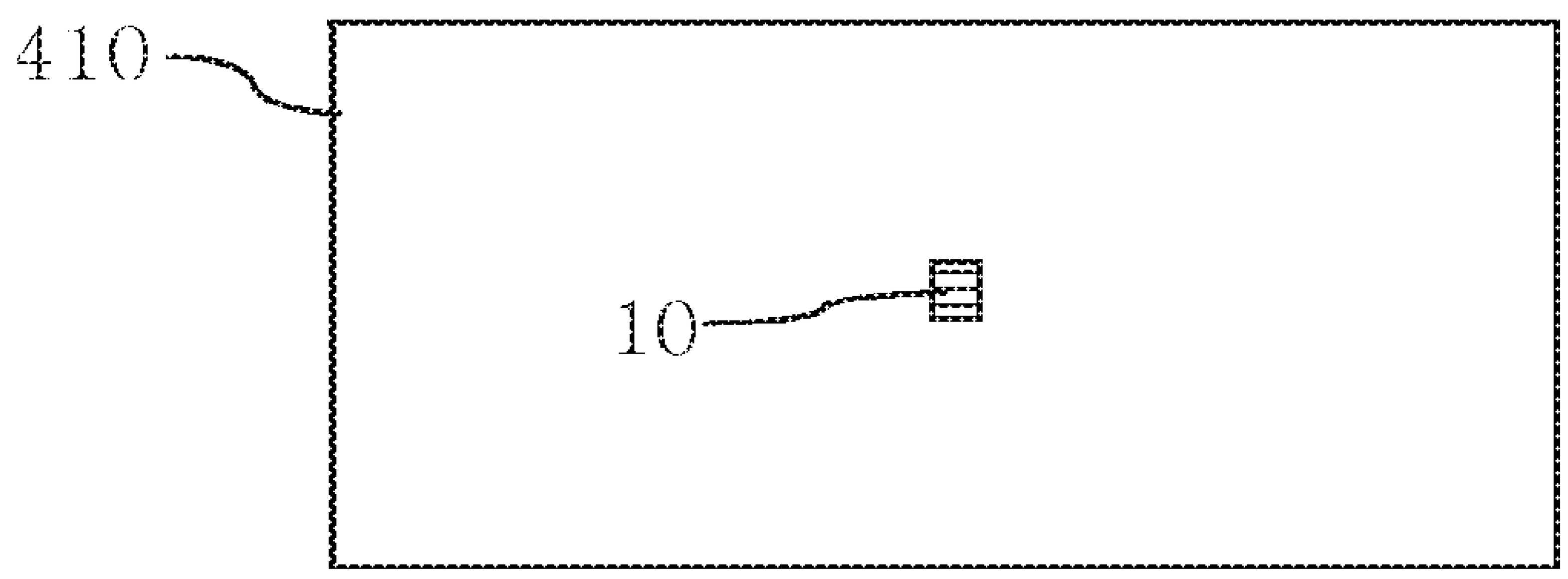

FIG. 24

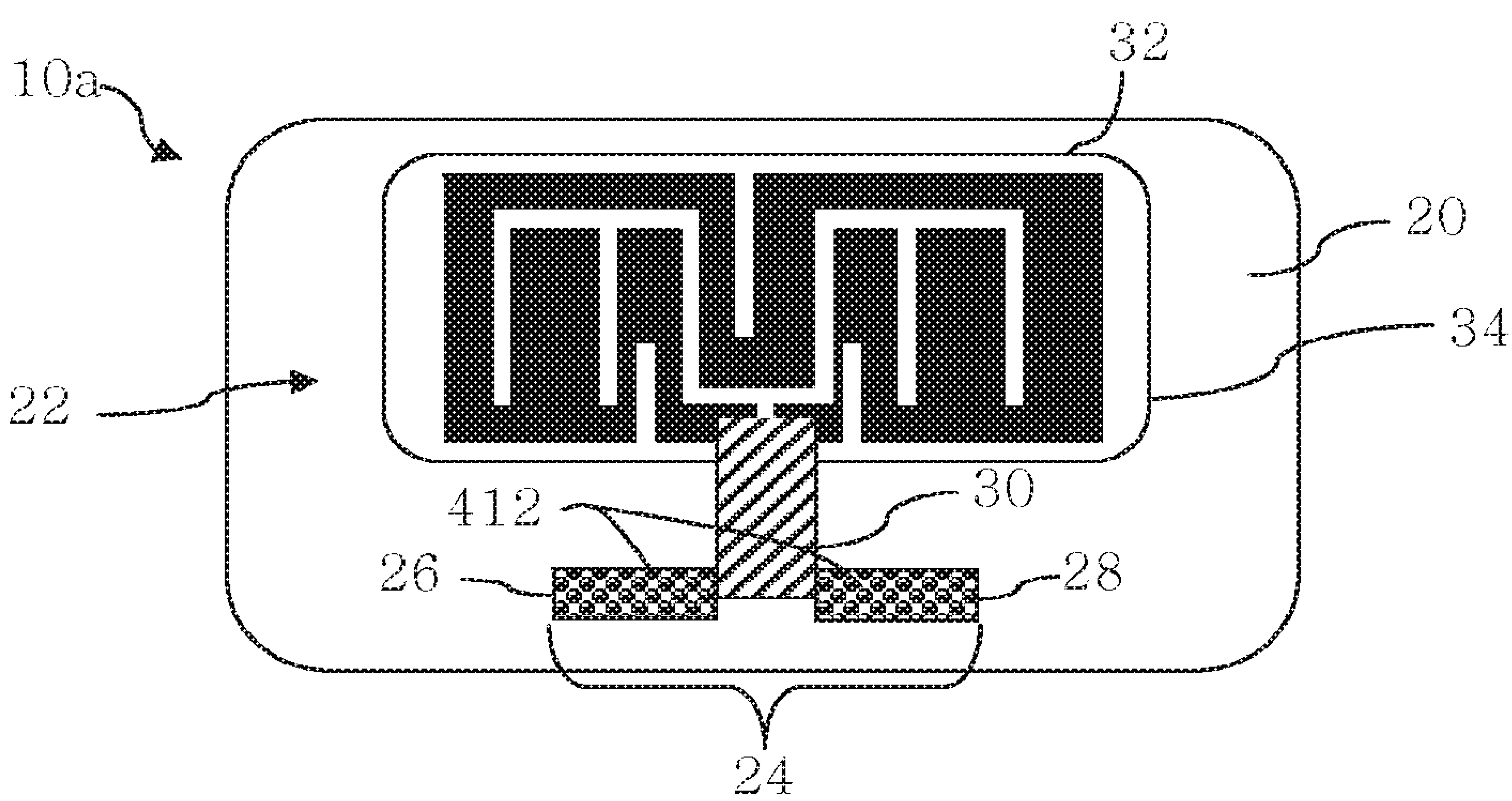

FIG. 25

WETNESS SENSORS, WETNESS MONITORING SYSTEM, AND RELATED METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of U.S. patent application Ser. No. 14/233,564, filed Feb. 11, 2014, which is a national stage application of International Application No. PCT/US2012/047712, filed Jul. 20, 2012, which claims priority to U.S. provisional Application No. 61/509,774, filed Jul. 20, 2011 and titled "A Self-Powered Disposable Wetness Sensor and Response System and Related Methods" and U.S. provisional Application No. 61/512,071, filed Jul. 27, 2011 and titled "A Self-Powered Disposable Wetness Sensor and Response System and Related Methods," all of which are hereby incorporated by reference in their entireties.

FIELD OF THE INVENTION

This invention relates to liquid sensors capable of transmitting remotely detectable signals. More particularly, it relates to liquid sensors with improved signal transmission properties and improved liquid flow management properties.

BACKGROUND

Enuresis, or urinary incontinence (UI), is a health condition affecting many individuals. It is the leading cause of patient admission to a long-term care facility. UI can lead to a variety of medical problems that dramatically increase the cost of care. As a result of prolonged exposure to moisture from UI, perianal skin damage occurs and can progress rapidly to ulceration and secondary infection, including bacterial and yeast infections that increase discomfort and treatment costs. The standard of care required in most long-term care facilities is to check each patient at least every two hours and change them when needed. While this practice ensures a patient should go no longer than two hours without attention, it still leaves as much as a two hour window of wetness exposure should the patient wet shortly following an initial check, putting patients at significant risk of skin breakdown and disrupted sleep during the night. This method also requires staff to waste time checking patients who do not need assistance.

SUMMARY

Although many liquid detecting sensors capable of remotely alerting a caregiver, via radio frequency signals, when a wetness event occurs are known, many of them suffer from drawbacks related to the way the signals are transmitted between the sensors and detectors and the way liquid is transported to the sensor. They also do not provide the ability to determine the degree of wetness or the type of liquid in proximity to the sensor.

The inventors have devised a self-powered powered wetness sensor that uses the liquid to power the sensor's electronics. The sensor's electronics are also configured to include representations of these electrical parameters in the data transmission. Because the electrical parameters vary depending on the degree of wetness and/or type of liquid, the sensors are able to provide this valuable information.

In a preferred embodiment of the sensor, these advantages are achieved by providing a sensor comprising a substrate having a plurality of electrodes, a circuit, and a transmitter thereon. The plurality of electrodes are coupled to generate electrical power when in contact with liquid. The circuit is electrically connected to the electrodes so as to be activated by the electrical power, detect an electrical parameter of the electrical power, and generate a plurality of data packets indicating a degree of wetness corresponding to the detected electrical parameter. The transmitter is electrically coupled to the circuit to receive the plurality of data packets and transmit representations of the plurality of data packets as electromagnetic signals.

Another aspect of the invention is a liquid absorbent wetness sensor that includes one or more of the sensors placed between a plurality of layers of material that receive liquid discharge, such as urine, from a wearer. A preferred embodiment of the liquid absorbent wetness sensor comprises a liquid transport layer positionable next to the skin of a wearer and capable of transporting a volume of liquid discharged by the wearer away from the wearer's skin; a liquid absorbent layer that receives the transported liquid; and a liquid sensor in liquid communication with the liquid absorbent layer. The liquid sensor comprises a galvanically energizable power source capable of activating a remotely detectable signal in response to liquid in the liquid absorbent layer. A liquid management layer is positioned between the liquid transport layer and liquid absorbent layer. The liquid management layer comprises a material that retards liquid flow between the liquid transport layer and liquid absorbent layer so as to prevent the sensor from being energized until the volume of liquid is large enough to flow to the liquid absorbent layer and energize the power source. Here, the liquid management layer is particularly advantageous as it prevents the sensor from being activated unless a substantial wetness event occurs.

In yet another aspect of the invention, the sensor is included in a wetness monitoring system in which one or more transceivers are adapted to receive the plurality of data packets and communicate data over a communication network to an electronic database. The electronic database forms part of a control computer system that can alert a monitoring agent, such as a caregiver, if wetness is sensed. Thereby, allowing the monitoring agent to quickly address the issue.

In a method aspect of the invention, a preferred method of detecting liquid comprises detecting the presence of liquid in proximity to a sensor, the sensor having a substrate with a plurality of electrodes, a circuit, and a transmitter positioned thereon. The electrodes are coupled to generate electrical power when in contact with liquid. The circuit is electrically connected to the electrodes so as to be activated by the electrical power, detect an electrical parameter of the electrical power, and generate a plurality of data packets indicating a degree of wetness corresponding to the detected electrical parameter. The method further comprises receiving a transmitted signal from the sensor, the signal including representations of the plurality of data packets. Other features of the include determining an amount of liquid in proximity to the electrodes by correlating the detected electrical parameter with a wetness value and/or determining a type of liquid in proximity to the electrodes by correlating the detected electrical parameter with a liquid type.

These and other aspects, embodiments, and advantages of the invention will be better understood by viewing the drawings and referring to the following discussion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagram of a first embodiment of wetness sensor in combination with a detector in accordance with an aspect of the invention;

FIG. **2** is a top plan view of the first embodiment of the wetness sensor in accordance with an aspect of the invention;

FIG. **3** is a side elevation view of the wetness sensor of FIG. **2**;

FIG. **4** is a top plan view of a second embodiment of a wetness sensor in accordance with an aspect of the invention;

FIG. **5** is a side elevation view of the wetness sensor of FIG. **4**;

FIG. **6** is an exploded view of a first embodiment of a sensor assembly, highlighting its method of construction in accordance with an aspect of the invention;

FIG. **7** is a side cross-sectional view of a second embodiment of a sensor assembly in accordance with an aspect of the invention;

FIG. **8** is a side cross-sectional view of a third embodiment of a sensor assembly in accordance with an aspect of the invention;

FIG. **9** is a top exploded view of a fourth embodiment of a sensor assembly in accordance with an aspect of the invention, in which the top layer is cut-away to provide a better view of the liquid management layer;

FIG. **10** is a side cross-sectional view of the sensor assembly of FIG. **9**;

FIG. **11** is a top exploded view of a fifth embodiment of a sensor assembly in accordance with an aspect of the invention, in which the top layer and an acquisition and distribution (ADL) layer are cut-away to provide a better view of the elongated sensor;

FIG. **12** is a top perspective view of the interior of a diaper having a sensor assembly thereon in accordance with an aspect of the invention;

FIG. **13** is a top perspective view of the interior of a diaper having two sensor assemblies thereon in accordance with an aspect of the invention;

FIG. **14** is a top exploded view of a sixth embodiment of a sensor assembly in accordance with an aspect of the invention, in which the top layer, liquid management layer, and ADL layer are cut-away to provide a better view of the elongated sensor;

FIG. **15** is a diagram of a person wearing an undergarment in the form of a diaper having a wetness sensor attached thereto in accordance with an aspect of the invention;

FIG. **16** is a top exploded view of a portion of an undergarment having a sensor assembly installed therein in accordance with an aspect of the invention, in which the top four layers are cut-away to provide a better view of the elongated sensor;

FIG. **17** is a top exploded view of a portion of another undergarment having a sensor assembly installed therein in accordance with an aspect of the invention, in which the top two layers are substantially cut-away to provide a better view of the ADL layer, which is partially cut-away to so that the sensor can be seen;

FIG. **18** is schematic of a wetness monitoring system in accordance with an aspect of the invention;

FIG. **19** is a flow diagram of an initialization protocol, which is an aspect of the wetness monitoring system;

FIG. **20** is a flow diagram of a user preparation protocol, which is an aspect of the wetness monitoring system;

FIG. **21** is a flow diagram of a wetness detection and reporting protocol, which is an aspect of the wetness monitoring system;

FIG. **22** is a flow diagram of a wetness alert protocol, which is an aspect of the wetness monitoring system;

FIG. **23** is a side elevation view of a liquid collection bag including a plurality of wetness sensors for measuring the amount of liquid in the bag in accordance with an aspect of the invention;

FIG. **24** is a side elevation view of a wound dressing including a wetness sensor in accordance with an aspect of the invention; and

FIG. **25** is a top plan view of the wetness sensor embodiment of FIGS. **2** and **3**, showing coated leads.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In the Summary above and in the Detailed Description of Preferred Embodiments, reference is made to particular features (including method steps) of the invention. Where a particular feature is disclosed in the context of a particular aspect or embodiment of the invention, that feature can also be used, to the extent possible, in combination with and/or in the context of other particular aspects and embodiments of the invention, and in the invention generally.

The term "comprises" is used herein to mean that other ingredients, features, steps, etc. are optionally present. When reference is made herein to a method comprising two or more defined steps, the steps can be carried in any order or simultaneously (except where the context excludes that possibility), and the method can include one or more steps which are carried out before any of the defined steps, between two of the defined steps, or after all of the defined steps (except where the context excludes that possibility).

In this section, the invention will be described more fully with reference to certain preferred embodiments. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will convey preferred embodiments of the invention to those skilled in the art.

Before describing the specific aspects and preferred embodiments of the invention in detail, some of the general principles related to the invention are first discussed. A particularly important aspect of the invention is a compact self-powered wetness sensor that may be incorporated into an insert that can be placed inside undergarments such as diapers or briefs to detect wetness therein. The sensor may alternatively be integrated with the undergarment.

In an institutional setting, such as a hospital or convalescent home, the sensor may be attached to patients who suffer from incontinence so that wet diapers, for example, can quickly be addressed by the patients' caregivers. In such settings, an electronic transceiver may be assigned to each sensor being monitored or to a specific location or room. The transceiver contains wireless reception and transmission electronics and is battery powered. The transceiver may be placed remote from the patient or attached to the patient. If the transceiver is attached to the patient, it may be desirable to include a temperature sensor, an accelerometer, a GPS receiver or other geographic location unit to detect the patient's movement and orientation. A single transceiver can preferably communicate with multiple sensors.

The transceiver may also communicate with a computer database via standard wireless protocol and identify its location and item being monitored. The computer system associated with the database acknowledges the transmission and establishes or continues a data file dedicated to that item. The data file includes each transmission's purpose plus the time and date of the transmission. Examples of "transmission purposes" include but are not limited to: sensor has been installed, low receiver battery, accelerometer inactivity, excessive or unexpected accelerometer movement, degree of wetness, "wetness threshold reached" alert, final transmission from a sensor, initial transmission from a sensor, patient location information, movement outside allowed range, and/or patient requires assistance. This information may then be made available for review electronically by any device with authorization for access to that data.

When the item being monitored experiences a liquid insult, the sensors' galvanic cell is activated by the liquid, thereby providing power to the sensor's electronics. After a delay for sensor stabilization and power integration, the sensor begins transmitting data packets at timed intervals proportional to the wetness being sensed or transmits information about the wetness-dependent analog output of the galvanic cell, including but not limited to voltage, amperage, impedance, or capacitance. The data bursts may include a sensor identification code when applicable. The transceiver previously assigned to this sensor receives the data burst, identifies the sensor, initiates the local data table, and records the actual first moment of liquid detection in the database.

The transceiver then attempts to relay this information wirelessly to the database assigned to this item. If the transceiver is not within range of a communications network, it will periodically resend the data until an acknowledgement is received from the computer system. New event data will cause the transceiver to transmit additional data. The data may include the amount of fluid leaked, the general type of fluid leaked, and the number of incidences.

Meanwhile, the sensor continues to periodically send data packets, repeating the sensor wetness information. Several methods of sending information from the sensor are feasible. In one embodiment, the information related to the sensor is transmitted via inter-pulse timing. The pulse rate will be faster when more liquid is detected. For example, if the sensor experiences additional liquid insult, the period between bursts is reduced and the transceiver records this as an additional wetness event. The transceiver then transmits this new data to the database. In another embodiment, the analog value corresponding to the degree of wetness received from the sensor is transmitted digitally to the transceiver. Many different protocols or transmission methods are possible between the sensor and transceiver. The sensor transmits data via RF transmission or fluid conduction. The conduction mechanism operates through the use of small amplitude electrical bursts that can be read by the detector with conductive pads in contact with the same fluid as the sensor.

Since the transmitted information is typically very small, it can be transmitted very rapidly, for example in microseconds. In one embodiment, multiple sensors communicate simultaneously with the use of communications slots through an anti-collision protocol. The transceiver transmits a clock signal with periodic information indicating the start of the first slot. Each sensor that detects this timing information randomly selects a slot and communicates its information during this time period. Since the number of slots can be very large (easily 1000 while maintaining efficient communication throughput), the random chance of any two sensors selecting the same slot is essentially zero. When communication is properly received by the receiver, it can send information to the sensor indicating that the information was received properly. If the sensor does not receive this handshake, the sensor may be colliding with another sensor and can randomly select another slot. As known in the art, many other methods of using two-way communication to allow communication of multiple senders of information are possible.

When integrate and fire communication is utilized, the system leverages the small burst size relative to the total time available to transmit. In a one-way communication scenario, the sensors send data packets at random start times and the receiver partitions the pulse trains with various algorithms. One such suitable algorithm called "independent component analysis" looks for patterns in the repetitive nature of the signals and finds the independent sources without knowledge of the number of sources or the identity of the sources. With two way communication and integrate and fire communication, the data packets can be synchronized to slots defined by the transceiver's clock signal. Data packets are integrated until a threshold is reached and then the transmission occurs only when its assigned (randomly or by the master receiver) slot arrives next.

The sensor preferably has a generally planar form factor, with small 3D features defining the sensor circuitry, such as metallization areas, an electronic bursting circuit, various coatings, and the like. The generally planar geometry allows the system to be used in a number of applications, such as those described herein. The sensor may be fully three-dimensional to help facilitate signal directionality, allow for fluid management structures, or allow for more appropriate placement.

The various aspects and embodiments of the invention have many advantages. Some but not all of those advantages are now described. Not every aspect and/or embodiment of the invention is require to achieve all of these advantages.

The wetness sensor itself has many advantages. Because it is only activated through liquid contact it has a nearly unlimited shelf life. Some embodiments of the sensor are compact, flexible, and disposable.

Liquid flow control techniques used in certain embodiments of the sensor assemblies use a unique combination of standard diaper materials to direct the flow of liquid to or from the sensor as needed. This allows large areas to be monitored with the minimum number of sensors.

Integrate and fire RF technology allows for battery-less operation (energy harvesting) while allowing enhanced range of detection. It also provides for enhanced data transmission by incorporating information in the pulse timing of the data stream.

The cost of making the sensors is exceptionally low, which makes the sensors more amenable to being disposed of after user.

A more detailed description of these aspects and embodiments of the invention are now discussed.

A. Wetness Sensor

Referring initially to FIG. **1**, a self-powered wetness sensor **10***a* in accordance with an embodiment of the invention self-generates the electrical power needed to operate its circuitry when it comes into contact with a conductive liquid L. The sensor's circuitry uses this power to transmit an electromagnetic signal **12** to a remote electromagnetic detector **14**. The signal **12** includes information about the wetness event that generated the conductive liquid L. Additional details of the sensor **10***a* and an alternate embodiment thereof are now described in connection with FIGS. **2**-**5**.

The wetness sensor **10***a* embodied in FIGS. **2** and **3**, includes a substrate **20** with sensor electronics **22** located thereon. The sensor electronics **22** include a galvanic cell **24** equipped with a first conductive lead **26** and a second conductive lead **28**. The conductive leads **26**, **28** of the galvanic cell **24** are in electrical contact with an integrated circuit **30**, which is in electrical contact with an antenna **32**. An electrically insulating layer **34** is placed over the sensor electronics **22**, but leaving the galvanic cell **24** exposed. While not always required, an attachment member **36** for attaching the sensor **10***a* to a desired surface may be placed on the side of the sensor **10***a* opposite the sensor circuitry **22** as represented in FIG. **2**. Suitable attachment members **36** include adhesives, adhesive tapes, hook and loop-type fasteners, or the like.

The sensor **10***a* may be constructed very small or very large, depending on what is desired. For many applications, it is desirable to use very small sensors having dimensions on the order of centimeters or millimeters. In a preferred embodiment, the sensor **10***a* is about 2 cm along its length and about 1 mm thick.

Referring now to FIGS. **4** and **5**, a sensor **10***b* having an increased wetness detection area A, according to an embodiment of the invention, includes a substrate **20**, sensor circuitry **22**, galvanic cell **24** equipped with a first conductive lead **26** and a second conductive lead **28**, integrated circuit **30**, antenna **32**, and electrically insulating layer **34**; all of which are configured to operate in the same fashion. The substrate **20**, however, is elongated to accommodate a plurality of conductive lead extensions **40**. The conductive lead extensions **40** are in electrical contact with the leads **26**, **28** such that, when the lead extensions **40** come into contact with a conductive liquid, the galvanic cell **24** generates electricity.

The substrate is preferably made of a thin flexible material, including various polymers. Examples of suitable materials include, but are not limited to, polyesters, polyolefins, polyimides, acrylics, vinyls, and papers.

The electrically insulating layer is preferably made of a thin flexible material, including various polymers. Examples of suitable materials include, but are not limited to, ethylcellulose, epoxies, silicone, and PETE (TEFLON).

In either embodiment of the sensor **10***a,b* The galvanic cell **24** self-powers the sensor **10***a,b* when it becomes wet with a conductive liquid, which may include bodily liquids such as urine, blood, or any other ion containing liquid, for example. This is because the conductive liquid forms electrical contact between the conductive leads **26**,**28**.

In a preferred embodiment, the galvanic cell **24***b* creates a measurable analog output such as current, voltage, or resistance in various wetness situations. When wet, the galvanic cell **24** supplies electrical power to the sensor **10***a,b*. The galvanic cell **24** will begin powering the integrated circuit **30** as soon as it is wetted. This, in turn, operates the antenna **32** which transmits the electromagnetic signal **12** that can be read by the electromagnetic signal detector **14**.

The conductive leads **26**,**28** are preferably made of different metals or compounds having different reduction/oxidation potentials similar to the anode and cathode of a battery. When the conductive leads **26**, **28** are placed in a conductive liquid, an electric voltage and current are generated. The materials used to make the leads **26**, **28** may be chosen from any number of metals and/or conductive carbon-based inks. Preferred first conductive lead **26**/second conductive lead **28** combinations include: carbon-based ink/zinc, silver/zinc, copper/zinc, silver/magnesium, copper/magnesium or the various salts thereof (silver chloride or silver phosphate, for example).

If desired, metals used for the leads **26**,**28** can be transformed by a number of chemical or physical reactions to produce a new chemical compound or material state/character (phase, crystallinity, surface texture). By way of example, silver may be transformed to silver phosphate by electrostatically applying a positive voltage to a silver film in the presence of phosphate ions. Thus, a silver phosphate cathode may be used with a zinc anode to form a galvanic cell. The new compound yields a change the differential voltage compared to non-transformed electrodes. Magnesium and zinc can be combined by vapor deposition or other methods to create a magnesium/zinc anode. Taking advantage of other changes in the lead **106**,**108** are also contemplated. These changes include: phase transitions, state transitions, structural changes, and other materials transitions that cause a change in the electrical output of the galvanic cell. Transformation can occur on the anode or cathode of the galvanic cell.

For high peak current loads, additional capacitance may be added to the sensor circuitry **22**. The capacitance can be added to the integrated circuit **30** the sensor itself **10***a,b*, or the substrate **20**. For example, the printed tracings between the galvanic cell **24** and the integrated circuit **30** may contain two printed metallic plates separated by a dielectric that produces a capacitance that will store sufficient charge to handle the peak current loads. Other methods of adding capacitance are also possible.

The galvanic cell's **24** source resistance or voltage may be used a gauge of the amount of wetness in the vicinity of the sensor **10***a,b*. The current draw will begin to pull the galvanic cell **24** voltage below the peak operating voltage in two scenarios: (1) when the galvanic cell **24** is loaded down at its output at the integrated circuit **30**, and/or (2) when the amount of conductive liquid is insufficient to maintain the electrochemical reaction between the leads **26**,**28**. Either or both scenarios will yield an output voltage and, therefore, the determined source resistance, that varies with the amount of liquid presented to the sensor **10***a,b*. The cell voltage is a function of the nature of the ionic fluid and the degree of wetness connecting the leads **26**,**28**. In addition to any instantaneous wetness, by the use of liquid flow control, the amount of liquid connecting the leads **26**,**28** can be made to dissipate over time. The degree of wetness of the surrounding environment of the galvanic cell **24** can affect the speed at which the liquid dissipates in the immediate area of the galvanic cell **24**. As the liquid dissipates, the galvanic cell's **24** internal resistance increases and can be used as an indicator of wetness. The degree of wetness and the dissipation phenomenon are converted to a proportional time interval spacing of transmitted data packets.

The voltage produced by the galvanic cell **24** may also be influenced by the galvanic cell's **24** geometry. For example, elongated parallel cell leads **26**,**28** produce a real resistance change in the galvanic cell **24** when exposed to the conductive liquid. As the liquid comes into contact with the sensor **10***a,b*, the leads **26**,**28** become increasingly wetted and capable of generating current. The current or voltage at a given wetted area can then be measured. The output voltage for the galvanic cell **24** is then measured by the integrated circuit **30**.

Accordingly, the galvanic cell's **24** voltage, current, and/or resistance provide valuable data points that can be used to infer the degree of wetness in the vicinity of the sensor **10***a,b*. In order to be useful, however, these data are preferably transmitted from the antenna **32** to the detector **14**. In practice, the integrated circuit **30** transmits this information to the detector via the antenna **32** using data bursts at a given time period. A data packet's characteristics are dependent on the input voltage from the galvanic cell **24**. Other suitable methods for communicating this data from the sensor **10***a,b* to the detector **14** include digital methods and conventional methods that vary frequency or amplitude.

The chemically or physically altered leads **26**,**28** may also be used to distinguish different conductive liquids. Differing wetness liquids, by their ionic concentration and/or atomic composition, may alter the output electrical characteristic of the galvanic cell **24**. For example, the galvanic cell **24** in the presence of urine may produce only 1 V, but in the presence of spilled juice it may produce 1.4 V. Likewise, the current or internal resistance of the galvanic cell **24** may change depending on the type of wetness.

In this context, a particularly advantageous use of the sensor **10***a,b* is as a diaper wetness sensor. In this case, the galvanic cell **24** may be used to discriminate between urine and spilled beverages and transmit a signal to the detector **14** only in response to urine.

The integrated circuit, **30** measures the voltage across the leads **26**,**28** and generates a signal **12** that is transmitted to the detector **14** if and/or when the target electronic reading is reached in the vicinity if the wetness source. If the sensor **10***a,b* is not close enough to the wetness source, the voltage will not change appreciably as no chemical transformation will proceed. Thus, the voltages can be transmitted via the sensor **10***a,b* to the detector **14** to confirm the that liquid detected is one of concern.

Conventional wetness sensors are typically highly complex when designed for analyte specificity or are too simplistic and therefore not analyte-specific. Material transformation of the leads **26**,**28** allows for increased specificity, especially for the limited range of chemicals typically found in the human body. Furthermore, many pH sensors, potentiometric sensors, actuating sensors, optical/fluorescent sensors, or otherwise require power to analyze incoming signals. Being a system that requires no input energy (and can in fact power a cell in itself), our materials transformation wetness sensor keeps parts and design complexity to a minimum. For additional capabilities, sensors that require only microamps of current are also suitable, as they can derive power from the galvanic cell **24***a,b*.

The sensor **10***a,b* may store energy that allows it to use the galvanic cell **24** in a manner that measures resistance or capacitance or test various species using simple coatings. The sensor **10***a,b* may be coated with one or more coatings selective to ions, molecules, electropotential, polarity, charge, or solvents. In an exemplary embodiment, a polyurethane coating that is selective for chloride ions is coated over the leads **26**,**28** allowing the sensor **10***a,b* to be used for checking for the presence of salts such as those found in incontinence events or for impurities in drinking water.

Urease may be used as an analyte-selective electrochemical sensor to produce an added electrical impulse in the presence of the urea in urine when used in conjunction with various field effect transistors (FETs).

In yet another exemplary embodiment, the leads **26**,**28** are coated with a material that only dissolves in the presence of certain desired liquids.

Referring to FIG. **25**, the sensor **10***a* includes a coating **412** placed over the leads **26**,**28**.

The voltage output of the galvanic cell **24** can be measured by the integrated circuit **30** and transmitted to the detector **14** as part of a data packet that indicates the type of liquid encountered and/or the degree of wetness.

The integrated circuit **30** implements a very low power, low bandwidth communications circuit that requires low voltage (~1 V) and low power (~10 uW). Input power can be supplied by a variety of energy harvesting techniques.

In some instances, the voltage level of the galvanic cell **24** may not have sufficient dynamic range to determine accurate sensor information (e.g. wetness). By placing a resistive load inside or outside the sensor circuitry **22**, the voltage level can be modified to provide better information from the sensor **10***a,b*. In some cases, it may be desirable to toggle the resistive load on and off to allow power to flow freely to the sensor circuitry **22** during normal operation but to add the resistive load only when the voltage level is being measured.

A drawback to using the very small galvanic cells **24** is that there are significant limits to obtaining steady-state voltage and current. To overcome this drawback, an energy harvesting technique, called "integrate and fire" has been chosen by the inventors as the preferred signaling method. Conventional RF output signaling requires significantly more power than a small galvanic cell can generate but the amount of information that must be transmitted can be done so in a very short period of time, typically within microseconds. The design goals met using the integrate and fire technology allow for a **1000** to **1** benefit in transmission burst output power.

The voltage output of the galvanic cell **24** can also be used to directly modulate or modify the signal being transmitted to the detector. In a preferred embodiment, using the "integrate and fire" methodology, the burst rate of the sensor **10***a,b* is modified by the voltage level of the galvanic cell **24**. An analog circuit including resistors, capacitors, and transistors is used to store the electrical power generated by the galvanic cell **24** until a threshold value is met. Once the threshold value is met, the electrical power is released to power the sensor circuitry **22** and thereby transmit the signal burst. The integrate and fire technique facilitates ultra-low power transmission capabilities while allowing valuable information to be incorporated in the configuration of the transmitted data stream. The integrate and fire technique has multiple objectives, including providing a sensor **10***a,b* having ultralow power consumption, low cost, and a very small form factor.

The "integrate and fire" transmission techniques utilized herein achieves the ultralow power transmission in relatively high RF noise environments. This technique is practical because the amount of data being transmitted is relatively small while the time available to transmit it is relatively long. In practice, the voltage output of the galvanic cell **24** powers the integrated circuit **30** and additionally charges a charge integrating capacitor. While the integrated circuit **30** manages the electrical activity, the integrating capacitor is charging. On command from the integrated circuit **30** when a voltage threshold is reached, the charged capacitor is connected to a voltage multiplying circuit which drives the antenna **32** with an output pulse duration several orders of magnitude shorter than the charge time. The available RF power in the transmitted pulse is a function of the relative duration of the charge time to the discharge time multiplied by the efficiency of the voltage multiplier plus the transmitter circuit.

By monitoring the time duration between pulses, the charge rate of the charge accumulating capacitor can be determined. If the electrochemical cell has a high source impedance, indicative of a low degree of wetness, the capacitor takes longer to charge. The time between succeeding RF transmission bursts therefore is an indication of the degree of wetness the sensor **10***a,b* is detecting. By utilizing and controlling the time domain as an indication of transmitted analog data, significant improvements in ultralow power transmission in high RF noise environments are achieved.

Because the sensor **10***a,b* can operate at very low power, it may be embedded in host systems for prolonged periods of time until wetness activates the galvanic cell **24**, causing the sensor to transmit an RF signal with a range far exceeding that which passive RFID systems can achieve.

A second objective of the integrate and fire concept adopted herein is to control the time interval between the transmission bursts as an indicator of the value of the input signal being monitored.

Differing voltages or current capabilities of the lead-liquid combination produce different signal burst rates. Similarly, different burst lengths, amplitudes, or frequencies can be created based on the voltage or current of the lead-liquid combination. These methods produce a self-powered transmission of the sensor value to an remote detector. These signaling methods are preferably built into the integrated circuit **30**. Preferably, the integrated circuit **30** circuits electronics that are printed onto a flexible substrate producing a very small, flexible, and substantially planar sensor transmission system.

An alternative approach to self-powering the sensor **10***a,b* is a battery that can be water-activated and embedded in a RFID tag. An example of such a battery is described in U.S. Pat. No. 5,395,707, which discloses a primary reserve battery useful in sonobuoys on the ocean. The battery uses cuprous iodide as a cathode and magnesium as the anode in an array to provide voltage, amperage, and operational time equivalent to conventional lead chloride batteries. Once the sonobuoy is no longer useful as it deteriorates in the environment, no lead will be presented into the ocean. The structural frame members protect the cuprous iodide which is brittle in a rigid array and provides for proper venting of gas and sludge formation to insure efficient operation of the battery.

Other kinds of batteries activated by other liquids like water can be found in the literature. For instance, U.S. Pat. No. 4,185,143 discloses a water activated battery using a metal/organo-halogen couple wherein the anode and cathode are formed as planar members with a porous insulator sandwiched between. There are provided channels to allow the electrolyte access throughout the cell. The channels may be cut in the cathode or the cathode may be formed as discrete portions of cathode reactant material deposited on a current collector backing plate. The portions of U.S. Pat. Nos. 5,395,707 and 4,185,143 describing their respective batteries is hereby incorporated by reference.

There are also alternate means for sensing the presence of liquid aside from the galvanic cell **24**. For example, one or more low power sensors apart from the galvanic cell **24** may be used. A cathode of anode, for example, that is analyte selective, but is not responsible for providing the majority of the power are possible to use.

B. Wetness Sensor Assembly

In yet another aspect of the invention, a sensor **10***a,b* is incorporated into a sensor assembly having components designed to manage the movement of liquid in the vicinity of the sensor **10***a,b*.

Sensor assemblies made in accordance with aspects of the invention employ unique, yet simple, physical mechanisms for liquid management, utilizing inexpensive materials to gauge liquid levels and control liquid flow to the sensor **10***a,b* as desired.

By placing the sensor **10***a,b* in a sensor assembly of the invention, a simple solution to preventing false alarms due to nuisance wetting (sweat, trickles, condensation) is obtained.

The sensor assembly includes a plurality of material layers adapted to control the flow of liquid to the sensor **10***a,b*. The materials may include hydrophilic top layers, acquisition and distribution layers, absorbent layers, and non-absorbent backing layers. The sensor assembly may be made into an insert for a undergarment or diaper or as a feminine hygiene pad. Alternatively, it may be incorporated into the production process of diapers, either within the diaper or extra-diaper, as desired.

The sensor assembly is constructed using manufacturing techniques and layering similar to that used to manufacture feminine hygiene pads.

The material layers may be sheets, films, porous fabrics, coatings, gels, or the like. In one embodiment, two sheets of material comprise the liquid management and absorbent layers are affixed to opposing sides of the sensor. The layer materials may be chosen from any number of materials, including polymers, waxes, gelatins and fibers.

Referring to FIG. **6**, a sensor assembly **60***a* in accordance with an embodiment of the invention includes a sensor **10***a* located between a plurality of material layers. The arrows indicate the direction of wetness flow towards from the wetness source toward the sensor assembly **60***a*. The sensor assembly **60***a* includes a top layer **62**, liquid management layer **64**, absorbent layer **66**, and bottom layer **68**.

In use, the top layer **62** will be placed closest to the wetness source. The top layer **62** is preferably made of spunbond polyester for allowing liquid to pass through to the material layers beneath it while separating conductive liquid, such as urine, from the user's skin. The top layer **62** provides the top surface and overall shape of the sensor assembly **60***a*. The spunbond polyester material is commonly used as the top layer in diapers.

The liquid management layer **64** is particularly advantageous as it is adapted to prevent the sensor **10***a* from being triggered by 'nuisance events' such as moisture, humidity, urine drips, or sweat from the user. The liquid management layer **64** is preferably made of a water impermeable material such polyethylene or similar waterproof polymer. In the embodiment shown in FIG. **6**, the liquid management layer **64** is smaller than the top layer **62** and the absorbent layer **68** to allow liquid to move to the absorbent layer **68**.

As mentioned above, the liquid management layer **64** allows for greater functionality of the sensor assembly **60***a*. Because it protects the sensor **10***a* from direct wetting, it can allow for prevention of false alarms due to nuisance or small-volume wetness events.

Furthermore, the liquid management layer **64** also provides a degree of control in liquid sensing. In conjunction with the absorbent layer **66**, the liquid management layer **64** allows for control over the amount of liquid needed to trigger the sensor **10***a* to send a signal **12** reporting a wetness event. In an embodiment in which the sensor **10***a* is sandwiched between the liquid management **64** and absorbent layers **66**, the amount of liquid necessary to trigger the sensor **10***a* to send the signal **12** is related to the size of the liquid management layer **64**. A smaller liquid management layer **64** will allow liquid to reach the absorbent layer **66** at a position closer to the sensor **10***a* than would a larger layer.

The liquid management layer **64** may be of a number of shapes, geometries, and patterns that can enhance the degree of liquid sensing control. It can be shaped to help guide liquid towards the sensor **10***a* regardless of the user's spatial orientation. For example, it may have a number of open sections nearer to the sensor to act as an inlet for liquid absorption, especially in cases where the absorbent layer **66***a* might be impeded from distributing liquid to the sensor

10*a*. Thus, if a liquid insult occurs away from the sensor **10***a*, especially for male users, the liquid management layer **64** drains the liquid towards the sensor **10***a*.

The liquid management layer **64** may be composed of semi-permeable materials that can greatly limit liquid flow and prevent or delay the absorbent layer from saturating with nuisance wetness events such as trickles or small volume voiding. Alternatively, it may be a combination of layers of absorbent materials and liquid impermeable materials to absorb wetness but prevent direct wetting of the sensor **10***a*. The liquid management layer **64** is preferably made of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polystyrenes, acrylates, or other water-impermeable materials.

The size of a particular layer is contingent upon the amount of wetness to be sensed, the wetness area, and the material from which the layer is made. In general, the liquid management layer **64** is either smaller than the absorbent layer **66** but larger than the sensor **10***a* or has a porous or open structure that directs liquid to wet the absorbent layer **66** at specific sites. Liquid wetted directly atop the liquid management layer **64** traverses the surface of the liquid management layer **64** and wets the underlying absorbent layer **66**, which subsequently wets the sensor **10***a*. The liquid management layer **64** may also be used only to prevent direct wetting of the sensor **10***a* and liquid, but otherwise allowing the absorbent layer **66** to be wetted first.

The liquid management layer **64** may have holes in it to allow the majority of the conductive liquid to flow through it, essentially leaving only a mesh of material to collect fluids. This prevents fluid from accumulating at the sensor **10***a*.

The liquid management layer **64** may have fluid wicking arms/threads/tubes that collect fluid from a large area and draw it toward the sensor **10***a*.

In this embodiment, the sensor **10***a* is located between the liquid management layer **64** and the absorbent layer **66**. The sensor **10***a* is oriented with the back side of the substrate **20** contacting the liquid management layer **66**. The side of the sensor **10***a* on which the sensor circuitry is located abuts the absorbent layer **66**. This orientation allows for the leads **26**, **28** to be wetted by conductive liquid in the absorbent layer **66**.

In this embodiment, the substrate **20** is preferably less than 200 mm^2 in area. The leads **26**,**28** are made, respectively, from silver phosphate and magnesium. The leads **26**,**28** preferably have an area less than 9 mm^2 and are less than 0.25 mm thick. The antenna **32** is preferably made from silver particle ink printed onto the polyester substrate.

The absorbent layer **66** is preferably made of a hydrocolloid-type of material that swells when it absorbs water such as the hydrocolloid materials used in conventional diapers. Suitable materials capable of achieving this function include cellulosic materials. The absorbent layer **66** wicks the conductive liquid toward the sensor **10***a*.

The absorbent layer **66** allows for a wide area of sensing using a single small sensor **10***a*. The absorbent layer **66** effectively acts to transport liquids from remote areas of the sensor assembly **60***a* to the sensor **10***a*. Materials with rapid wicking or capillary properties, such as lateral flow strip material, are ideal for this embodiment. This allows for longer distance sensing than would be normally available.

Dryness sensors can be used in bags that empty rather than fill. The wicking agent can allow continuous transport of liquid in to a reservoir or additional absorbent layer. When liquid is no longer available, the wicking material empties and no longer signals liquid at the site.

The absorbent layer **66** may be made of liquid retaining materials that allow for the collection of small amounts of liquid and moisture over time. The liquid continually migrates towards the sensor **10***a* as additional liquid is collected. When enough liquid has been collected, the sensor **10***a* is triggered and a signal **12** is transmitted to the detector **14**. Thus, a user whose enuresis is in the form of minor wetting events may also allow a wetness signal to be triggered after sufficient wetting even when no singular wetting event may be sufficient for triggering a signal.

The bottom layer **68** is preferably made of the same material as the top layer **62** and is the same size as the top layer **62**. The bottom layer **68** allows liquid to pass through to the undergarment beneath and provides the bottom surface for the sensor assembly **60***a*. If desired an adhesive **70** may be applied to the bottom layer **68** for affixing the sensor assembly **60** to a undergarment **72** such as a diaper. If the sensor assembly is to be used in conjunction with standard diaper, the bottom layer **68** is preferably made of spun bonded polyester with hydrophilic characteristics. If, however, the sensor assembly **60***a* is to be used with a standalone liquid absorbing product, such as a undergarment insert, the bottom layer **68** is preferably made of propylene resin without any added surface surfactants. This cloth-like film prevents leakage out of the sensor assembly **60***a*.

Other arrangements of the sensor assembly are also possible. Referring to FIG. **7**, in an alternative embodiment of the sensor assembly **60***b*, the sensor **10***a* is incorporated into the absorbent layer **66** and the liquid management layer **64** is placed atop the absorbent layer **66***b*. The bottom layer **68** is located on the side of the absorbent layer **66**, that is opposite the liquid management layer **64**.

Referring to FIG. **8**, in another alternative embodiment of a sensor assembly **60***c*, the liquid management layer **64** encompasses the sensor **10***a* and absorbent layer **66**. In this embodiment, the liquid management layer **64** preferably includes minimally porous, swellable, or slowly degrading/dissolving materials, or any other materials that retard the flow of liquids without completely blocking them. Alternatively, the liquid absorbent layer **66** may encompass the liquid management layer **64** to prevent liquid from pooling over the liquid management layer **64**.

In yet another preferred embodiment of a sensor assembly **60***d* shown in FIGS. **9** and **10**, the liquid management layer **64** overlaps the absorbent layer **66** but follows its general shape and contour. A plurality of perforations **90** penetrate the liquid management layer **64** for allowing liquid to drain through the liquid management layer **64** towards the absorbent layer **66** in proximity to the sensor **10***a*. The arrows in the perforations **90** in FIG. **10** illustrate the direction of liquid flow. In FIG. **9**, the liquid management layer **64** is shown as being transparent in order to provide an understanding of where the sensor **10***a* is located.

The dimensions of the sensor **10***a* used in the sensor assembly may be adjusted as desired. Referring to FIG. **11**, a sensor assembly **60***e* in accordance with an alternative embodiment of the invention includes the elongated sensor **10***b*, the top layer **62**, liquid management layer **64**, absorbent layer **66**, and bottom layer **68**. This configuration is useful where the wetness area is large and the sensor assembly **60***e* replaces a feminine hygiene pad or acts as an insert for a female or child's diaper or panty.

The various embodiments of the sensor assembly are particularly useful as wetness detecting inserts for undergarments, including adult or baby diapers or briefs. FIG. **12**, shows a diaper **100** with a sensor assembly **60**, which could be any of the sensor assemblies **60***a-f* described herein, located in the crotch region thereof on the interior side of the diaper **100**. The sensor assembly **60** may be attached to the diaper **100** using an attachment mechanism **36** as described previously.

Shown in FIG. **13** is a diaper **100** with two sensor assemblies **60** located in the crotch region. This configuration may be advantageously employed in large diapers such as large adult male diapers. In the example shown in FIG. **13**, the sensor assemblies **60** are preferably the elongated sensor assembly **60***e* described in connection with FIG. **11** or the sensor assemblies described in connection with FIG. **14** below.

FIG. **14** shows an embodiment of the sensor assembly **60***f* that is particularly useful in this situation because it allows for the wetness sensing area to be very large. In an exemplary embodiment, the wetness sensing area is about 30 cm long and about 10 cm wide. The sensor assembly **60***f* construction is similar to the embodiment described in connection with FIG. **11** but with an added acquisition and distribution (ADL) layer **110** to control the flow of liquid toward or from the sensor or sensors as desired. The ADL layer **110** is conventionally used in many diaper designs. It is located above the absorbent layer **66***f* to move liquids to avoid leakage. In those cases where it is desirable to differentiate between an insult coming from the front of the diaper and an insult coming from the back of the diaper, multiple sensors **10***b* can be used and the ADL layer **110** is helpful in keeping those liquids separated.

C. Wetness Sensor Integrated into Undergarment

Referring to FIG. **15**, another aspect of the invention is a undergarment **120** such as a diaper or brief having one or more sensors **10** integrated therein. A typical example of the undergarment **120** construction, showing how a sensor **10** is integrated therein is best seen in the cut-away view of the undergarment **120***a* in FIG. **16**. The sensor **10** may be any of the sensor embodiments described herein. The undergarment **120***a* includes a plurality of many of the same material layers described in connection with the sensor assemblies. The undergarment **120***a* acts like a diaper to direct liquid away from the skin of the user and store it in an absorbent material. In such embodiments, therefore, the sensor **10***b* is incorporated into the material layers used to make the undergarment **120***a*. Accordingly, rather than being a undergarment **120***a* insert like the sensor assemblies, the undergarment **120***a* has the sensor **10***b* built in.

The undergarment **120***a* includes a top layer **62**, ADL layer **110**, absorbent core **122**, fluid management layer **64**, sensor **10***b*, and an absorbent layer **66**. The top layer **62** is preferably made of hydrophilic nonwoven polypropylene material. It allows the moisture to proceed through to the underlying layer while giving the user the feeling of dryness. The ADL layer **110** is typically located near the wetness source where urine is most likely to be deposited. The ADL layer **110** is in the form of a patch that spreads and/or moves liquids very quickly into the absorbent **66** layer and reduces the potential for leakage. The use and/or choice of materials used in the ADL layer **110** depends on the materials chosen for the absorbent layer **66**. Typical ADL forming materials are resin bonded nonwovens, air bond nonwovens, “curly” fibers found in certain “high loft” configurations like aperture film made of perforated plastic. This layer typically has a blue color when used in current diaper/brief manufacturing.

The absorbent core **122** is preferably made of a cellulosic pulp derived from pine trees or polypropylene-based synthetic fibers. It is often dispersed with super absorbent polymer (SAP) for extra liquid absorption. The thinner the absorbent core **122**, the more important the ADL layer **110** becomes for distributing moisture throughout the surface area to avoid clogging of the absorbent core **122**. In this arrangement, the sensor **10***b* is preferably oriented such that the leads **26**, **28** directly contact the fluid management layer **64**. The substrate **20** is preferably a semi-permeable material designed to intercept small quantities of liquid from getting to the sensor **10***b*. This eliminates false alert signals due to sweat or minor wetness events. The liquid management layer **64** overlaps the sensor **10***b* in such a way as to force liquid to move beyond its periphery and into the absorbent layer **66** prior to the liquid coming into contact with the leads **26**, **28**. The fluid management layer **64**, then, controls the speed and quantity of liquid that eventually reaches the leads **26**,**28**.

FIG. **17** is cut-away view of another embodiment of an undergarment **120***b* configured for those applications where the undergarment **120***b* will be worn throughout the night, thereby leading to the expectation that the undergarment **120***b* will be subjected to multiple urine insults. This embodiment includes a mechanism for liquid storage and release, thereby allowing for multiple insults to be monitored from a single sensor. When the undergarment **120***b* is wetted, the liquid is first stored in one or more liquid retention zones (chambers, etc.) until it can be released into the absorbent layer **66**. A sensor **10***b* is in contact with this liquid retention zone and signals an insult. Once all the fluid is desorbed from the chambers, the sensor **10***b* stops transmitting signals. Upon rewetting, the sensor **10***b* once again transmits a wetness event signal. This process is repeated until the sensor **10***b* is removed from the wetness zone.

The embodiment of the undergarment **120***b* of FIG. **17** utilizes a number of layers that constitute a fluid storage and release mechanism. It includes a top layer **62**, an ADL layer **110**, a liquid retention layer **124**, a sensor **10***b*, and an absorbent layer **66**. The top layer **62** allows liquid to penetrate, thereby giving the individual the feeling of dryness. The liquid then moves to the ADL layer **110**, where it is distributed over a large area to avoid clogging the absorbent layer **66** immediately below the point of liquid incursion. After passing through the ADL layer **110**, the liquid penetrates the liquid retention layer **124**.

The liquid retention layer **124** is preferably made from plastic film having a plurality of apertures **126** formed therein. The sensor **10***b* is oriented such that the galvanic cell **24** directly abuts the liquid retention layer **124**. The void spaces surrounding the apertures **126** catch large volumes of liquid until the liquid can be absorbed by the absorbent layer **66** located below the sensor **10***b*. When the liquid contacts the leads **26**,**28** the galvanic cell **24** generates electricity for sending a wetness alert signal to the detector **14**. If the volume of liquid is sufficient, the sensor **10***b* sends the wetness alert signal. When the liquid is finally absorbed by the absorbent layer **66**, the galvanic cell **24** becomes inactive until it is contacted by liquid from a subsequent insult.

To increase the voltage and/or current output of the galvanic cell **24**, the concentration of ionic species in the wetting liquid can be increased by incorporating cationic and/or anionic salts into one or more of the material layers of the undergarment or sensor assembly. The cationic salts may include, but are not limited to, Na, K, Al, Fe, Ca, Au, and/or Ag salts. The anionic salts may include, but are not limited to Cl, F, Br, sulfate, phosphate, and/or nitrate salts. In a preferred embodiment, one or more salts are incorporated into the absorbent layer **66** in the vicinity of the sensor **10***a,b*. In the alternative, the one or more salts are added directly adjacent to the galvanic cell **24** in an adhesive matrix that can become wetted in the presence of liquid.

The sensor **10***a,b* may be built inside a diaper during the diaper manufacturing process. For example, the sensor **10***a,b* may be added to the diaper's impermeable lining or atop the permeable fluid pass-through layer. Excess fluid not absorbed by the absorbent layer may pass onto the permeable layer and into the diapers wetness control system.

Additionally, using new electronic printing technology, the sensor **10***a,b* may be printed onto or into the diaper during diaper manufacturing.

Depending on the size and desired target area for wetness, more than two sensors and/or sensor assemblies may be used.

D. Computer-Based Wetness Monitoring System

The sensors, sensor assemblies, and sensor integrated undergarments described above are particularly useful when employed in a computer based wetness monitoring system. The inventors have developed a computer based wetness monitoring system that may be used by a monitoring agent, such as a caregiver, to monitor the wetness of a child or a patient, for example. A preferred system, in accordance with an aspect of the invention, allows the caregiver to receive an alert signal when a wetness event, such as urination or defecation, occurs, thereby allowing the caregiver to respond to the event quickly. As is described in greater detail below, one or more of the wetness sensors are affixed to the item to be monitored in such a position as to allow the one or more sensors to be insulted with the liquid to be detected. A receiver-transmitter (transceiver), assigned to detect electromagnetic signals from the wetness sensor is located within detection range of the RF signal transmitted from the wetness sensor. The transceiver is programmed with information specific to the item being monitored. When a wetness sensor is insulted, the galvanic cell powers the sensor and the sensor subsequently transmits a series of data to the transceiver. The data may include a code specific to the insulted wetness sensor, data representing the state or value received from the sensor, position or orientation information when available, and other data associated with the wetness sensor. The transceiver passes this data along with its identification to a remote database. The system may then be initialized and ready for the next wetness event or can wait until the wetness sensor or monitored device (e.g. diaper) is replaced before reinitialization. The transceiver may be worn by the user and placed remotely from the user.

Referring to FIG. **18**, a wetness monitoring system **200** in accordance with an aspect of the invention includes a wetness sensor **10**, a transceiver **202** and a control computer system **206**.

When the sensor **10** detects a wetness event, it generates and transmits data packets **208** separated by a time interval T, containing data about the wetness event to the transceiver **202**. The transceiver **202** is also capable of sending a transceiver signal **210** to the sensor **10**. In many implementations of the wetness monitoring system **200**, the sensor **200** is associated with an undergarment **220** worn by a user.

The transceiver **202** and control computer system **206** are able to communicate data back and forth via a network **204**. The network **204** may be an internet network and/or ethernet network, for example.

A monitoring agent **205** is capable of communicating with the control computer system **206** via the network **204**. This allows the monitoring agent **205** to receive wetness event alerts from the control computer system **206**. Monitoring agents **205** include but are not limited to patient or child caregivers such as medical personnel or parents, and any other party that is interested in receiving an alert when a sensor is activated.

The control computer system **206** includes an interface **212**, machine readable memory **214**, and database **216**. The control computer system **206** and its interface **212** and database **216** are realized by at least one processor **218** executing program instructions stored on the machine readable memory **214**. The system **200** is not limited to any particular number, type, or configuration of processors **218**, nor to any particular programming language, memory storage format or memory storage medium.

In implementations of the control computer system **206**, the wetness monitoring system **200** is not necessarily limited to any geographical location or networking or connection of the processors and/or storage media, provided that the processors and/or storage media are capable of cooperating to execute the interface **212** and database **216**. It is not required that the processors and/or storage media be commonly owned or controlled. Additionally, although the database **216** is referred to here as a single database, it is not necessary that it be located on a single memory media unit or at a single physical location. The database **216** may be divided into sub-databases for categorizing information if desired.

The database **216** includes information about the user, such as, for example, the user's identification, vital statistics, and wetness event history. It also includes information transmitted from the sensor **10** to the transceiver **202** regarding wetness events registered by the sensor **10**. Data may be entered manually into the database **216** via the interface **212**, which is a network connectable electronic device such as a computer, tablet computer, personal data assistant, mobile telephone, or the like.

Referring to FIG. **19**, the system **200** is initiated via an initiation protocol **228**. At block **230** the transceiver **202** is associated with a user and a particular sensor **10** or group of sensors being worn by the user. This allows the control computer system **206** to open a user data file in the database **216**. Data transmitted from a sensor **10** worn by the user to the transceiver **202** is stored in that particular user's data file.

By way of example, this may implemented in an institutional setting by manually entering information about the user via the interface **212**, including the user's identification and room number or location at the institution. The user is then assigned a transceiver **202** configured to communicate with the sensor **10** worn by the user.

At block **232**, the transceiver **202** is placed in the user's room and the network connection between the transceiver **202** and database **216** is verified by pressing a button on the transceiver **202**.

At block **234** the transceiver **202** communicates data to the database **216** via wireless repeaters placed throughout the institution to detect data transmissions from all of the various transceivers **202** assigned to other users at the institution. The initial data stream from the transceiver **202** to the database **216** reflects that fact that that it is an initialization data transmission. The initial data stream may also report the battery condition of the transceiver **202**. At block **236**, the control computer system **206** sends an ACK response to the transceiver **202**.

An added benefit of placing different transceivers **202** throughout the institution is that, should the user move to a different location in the institution, an alternate transceiver **202** will detect the user's movement and provide a form of user geo-tracking within the institution. When multiple sensors **10** are concurrently transmitting data through a common transceiver or multiple transceiver are operating in close proximity, data transmission is achieved using anti-collision RF protocol.

Moving now to FIG. **20**, a user preparation protocol **237** in accordance with an aspect of the wetness monitoring system **200** begins at block **238** where the sensor **10** is attached to the user in the form of an individual sensor attached to the user's undergarment **220**, a sensor assembly **60** placed in the user's undergarment, or an undergarment **120** having a sensor **10** integrated therein. At block **240**, the transceiver is powered-on and begins communication with the database **216**. At block **244**, the transceiver **202** transmits a transceiver identification signal to the database **216**, allowing the control computer system **206** to identify the appropriate user data file. The control computer system **206** subsequently records the identification, date, Lime, and reason for the transmission in the user data file (block **246**) and the transceiver receives an ACK response (block **248**). The transceiver **202** then enters stand-by mode while waiting to receive a signal from a sensor **10**.

FIG. **21** outlines a wetness detection and reporting protocol **252** in accordance with another aspect of the wetness monitoring system **200**. When user urinates or deffocates, a wetness event occurs (block **254**) and the liquid eventually comes in contact with the galvanic cell **24** (block **256**), which powers the sensor **10** (block **258**). The sensor **10** transmits a wetness event signal to the transceiver **202** (block **260**) the transceiver **202** subsequently receives the signal (block **262**). The transceiver **202** then communicates the wetness to the database **216** (block **264**) and receives an ACK response (block **268**) from the control computer system **206**, acknowledging that the data was received by the database. **216** Data about the wetness event that is recorded in the database **216** includes the date, time, and information about the wetness event. The transceiver reverts back to stand-by (block **270**). If another wetness event occurs, the detection and reporting protocol **252** is repeated.

In accordance with yet another aspect of the wetness monitoring system **200**, after a wetness event, the wetness alert protocol **272** in FIG. **22** may be initiated. In the alert protocol **272**, one or more monitoring agents receive an alert indicator (block **274**). The alert indicator may be in the form of an electronic message such as an email or SMS message sent by the control computer system **206** to the monitoring agent's network connectable electronic device and/or an audible alarm. The monitoring agent may then service the sensor **10** user (block **276**) by engaging the user, removing the soiled undergarment, and replacing the soiled undergarment with a new undergarment equipped with a sensor. The monitoring agent then resets the transceiver **202** (block **278**) by, for example, pressing a reset button on the transceiver **202**. The transceiver **202** subsequently reports to the control computer system **206** that the corrective action was taken (block **280**) and receives an ACK response (block **300**) from the control computer system **206**, acknowledging that the data was received by the database **216**. When the new sensor **10** is attached to the user, the system then **200** reverts back to the initiation protocol **228**.

The transceiver **202** may be pre-programmed to define the number of wetness events that must occur and/or the number of sensors that must be triggered before an alarm indicator is sent. This allows the monitoring agent to configure their particular application as they choose.

If the transceiver **202** is equipped with a GPS unit **132**, accelerometer **134**, and/or other electronic component such as a temperature sensor, the transceiver **202** may transmit location, accelerometer, and/or temperature data to the transceiver control computer system **206**. Preferably, to avoid false alarms, the transceiver is pre-programmed only to send such data to the control computer system **206**, when the data fall outside of certain atypical parameters. When an atypical reading occurs, however, the transceiver **202** transmits a signal to the control computer system **206** indicating the transceiver's **202** identification and reason for the transmission. The transmission is then recorded in the database **216**. The control computer system **206** may subsequently send an alert indicator to the monitoring agent.

With respect to the accelerometer **134**, because a user will typically move around often during the awake periods and seldomly during sleep, accelerometer **134** movements will become more predictable based on the movement history of the user. When the transceiver **202** is equipped with an accelerometer **134** transmits to the control computer system **206** an atypical movement such as a fall or sudden vibration, the control computer system **206** stores the information transmitted in the user data file. In addition, normal nocturnal movements of the user are typically indicative of normal sleep patterns. When these movements change beyond a pre-defined threshold, it can indicate a problem, unknown to the monitoring agent, that the user is experiencing. Events such as sleepwalking and falling out of bed or continuous movement while in bed can be detected by the accelerometer **134** as an indication of the need for immediate attention.

The database **216** may include one or more predictive algorithms designed to predict a subsequent wetness event based on a user's previous wetness events. In this case, the control computer system **206** may send an alert indicator to the monitoring agent, alerting the monitoring agent of the likelihood of an impending wetness event, giving it the ability to preclude said event by taking corrective action in advance. Predictive algorithms may utilize a variety of information including: subject toileting and wetting history, subject recent activity levels (e.g. sleep, wake, active), recent subject locations (e.g. cafeteria, bed, coffee shop), subject orientation, and subject-specific history and physical information that may be stored in the database **216**.

E. Odorant Sensing

In another aspect of the invention the wetness sensor is replaced with an odor sensor. Is this aspect, the arrangement of the previously described sensor assemblies, undergarments with integrated sensors, and the operation of wetness detection system are the same, except for the fact that the signal is transmitted to the detector in response to an odor, rather than wetness. The odorant (a chemical tag added to the wetness absorbing article) may include a number of scented or unscented volatile chemicals, including alcohols, ketones, thiols, esters, etc. The odorant is detected using a chosen sensor, which may be selected from among surface acoustic wave (SAW) sensors, metal-organic semiconductor (MOS) sensors, field effective transisitors (FETs), or chemoresistive sensors. The odorant causes a change in the physical or chemical state of the sensor which can be read and interpreted electrically by the sensor reader. The sensor device may have an odorant filter selective to the given chemical to be detected. The odorant may be chosen among those most unlike odors found in health facilities to prevent false positives.

An odorant that interacts with the chosen insult is first applied to a wetness absorbing article. An external odorant sensor, such as a MOS sensor, is powered and set to detection mode. As fluid is discharged into a wetness absorbing article, the fluid releases (via chemical reaction, dissolving of protective coating, aerosolization, etc.) the odorant gas into the surrounding article space. As the gas escapes from the article, the external sensor is triggered at a predetermined in-air concentration to signal the presence of the insult, indicating that the article must be changed or attended to.

In one embodiment, the odorant comprises alcohols entrapped within a water-dissolvable matrix. As urine passes over the matrix due to an incontinence event, the alcohol is released into the atmosphere. A sensor-transceiver worn by the patient on the diaper is triggered to the active signaling state by the presence of the alcohols in the environs and signals to the detector that a wetness event has occurred.

Decomposition products of urine, such as ammonias, may be chosen as the odorants. Various chemicals that hasten the production of such decomposition products may also be used to increase the concentration of the odorants at the sensor. The decomposition products of urine from biological decomposition factors, such as bacteria, can also be used as the odorant.

The odorants may be incorporated anywhere within an undergarment, such as a diaper, from the back-liner to the top layer. The odorant may be strategically placed within the garment to reflect wetting patterns. In the case of a diaper, should the caregiver desire that only full diapers be changed, the odorant may be placed only at the extremes of the diaper geometry, such as at the waist or along the edges of the article. In this manner, initial fluids will be absorbed in the central absorbent layers of the diaper. As the diaper reaches fullness, fluid will be forced to distribute to the edges of the garment where the odorant resides, thus triggering the odorant sensor and transmitting a wetness event as described herein.

Multiple odorants or taggants may be utilized to determine the location and/or level of saturation of the diaper. This information may be useful in predicting incontinence events since it will provide information each time an incontinence event occurs, along with a relative volume already absorbed in the diaper. Additionally, the quantity of taggants detected at the sensor may provide flow or volume information.

The chemical sensor may also be able to directly detect the odor from the event (urine or fecal matter), breakdown odors, or byproducts of the event interacting with the diaper without the need for a taggants or odorant added to the diaper.

The odorant may cause a physical change outside of typical electronic changes found in many sensors. In one embodiment, the sensor consists of a color/pattern change material and an optical detector. The color change may be from one hue/saturation/value to another or the colors may show up in a pattern that can be read similar to a barcode. The color change material may be in a state of permanence (replaceable), may last for a chosen duration, or may be reversible where the caregiver can reset the color/pattern change via application of voltage, current, chemicals, physical pressure, magnetization, or other means.

The optical detector may be a colorimeter, spectrophotometer, UV-Vis spectroscope, optical imager, pattern detector, barcode scanner, or the like. The optical detector periodically scans the color/pattern change material to conserve battery power. The optical detector may be separate from the wetted article or it may be applied to the article surface. In one embodiment, the optical detector is attached to the back of a disposable article and the color change is measured directly from the article. The monitoring agent is also presented with an optical mechanism of identifying wetness alongside with the electronic mechanism.

F. Sensor in Liquid Collection Bag

The sensor **10***a,b* may be placed into a liquid collection bag, such as a urine or other waste collection bag, or a fluid supply bags to indicate the presence of fluid in the bag. This can be used to determine when the bag is full or empty. Multiple sensors **10***a,b* built into the bag can be used to determine the rate of filling or percentage of fullness based on the timing of the firing of the sensors **10***a,b*. Furthermore, a single sensor **10***a,b* with a degree of wetness detection mode can also be used.

Referring to FIG. **23**, in accordance with an aspect of the invention, a liquid collection bag **400** includes a bag interior **402** defined by a plurality of bag interior walls **404**. Three wetness sensors **10** are vertically spaced apart along one of the interior walls **404** for detecting the level of liquid **408** in the bag **400**

The sensor **10***a,b* configuration implemented into collection bags can make use of the fluid management layer **64** and absorbent layer **66**. To avoid wetting the sensor **10***a,b* from incoming fluid drops or splashes, the fluid management **64** and absorbent layers **66** may take on a number of configurations. In one embodiment, the absorbent layer **66** is a thin membrane that runs the length of the collection bag while the fluid management layer **64** is a sheath that surrounds the sensor. The absorbent layer **66** absorbs sufficient fluid to trigger the sensor **10***a,b* at a given fluid height in the bag, signaling fullness. Fluid containers for lubricants, hydraulics, as well as blood or IV fluid are of the numerous applications for this concept.

Because the sensors **10***a,b* are inexpensive and shelf life of the galvanic cell **24** is very long, the sensors **10***a,b* can be built into the bags and remain inactive until wetted. A transceiver **202** may be attached to a bedside pole or other location to facilitate communication with other electronic devices to indicate problems or maintenance requirements (e.g. replace bag). The transceiver **202** may also be built into an existing monitor, such as an integrated patient monitor like a Philips Intellivue system.

G. Wound Care

Similar to wetness detection in a diaper, detection of moisture in a wound dressing is also important. In another aspect of the invention, one or more of the wetness sensors **10***a,b* are embedded into or attached to a wound dressing to indicate the presence of moisture or the amount of moisture present under or in the bandage. The sensor **10***a,b* may communicate with a transceiver **202** that communicates with a database **216** as described above. In the wound care application, differentiation between different fluid types such as blood, sweat, or pus for example, may provide additional information about the status of the wound (e.g. infected, healthy, actively bleeding).

Referring to FIG. **24**, a wound dressing **410** in accordance with an aspect of the invention, includes a wetness sensor **10** attached thereto.

Ion-selective electrodes that utilizes polymers such as PVC or polyurethane can detect a number of cations and anions. Furthermore, selective enzymatic coatings may be applied to selectively sense diaminobutanes and other chemicals that may signal necrosis due to infection. Such sensors may be worn as a wound dressing or as a simpler test strip.

Pathogenic bacteria or other infectious agents can themselves be sensed through the use of coatings, membranes, or antibody/antigen pathways. Microbial response in such a system is tested by ion transport through a bilayer lipid membrane-coated solid state electrode allows for selectivity and decreased source resistance in the electrode assembly, which is then captured by the sensor electronics and transmitted in the data stream or burst timing. Other embodiments include using biological recognition components such as receptors, nucleic acids, and antibodies with the appropriate transducer. Potentiometric and amperometric designs may also be implemented.

H. Lateral Liquid Flow Test Strip

The wetness sensor **10***a,b* may be incorporated into a lateral flow test strip or immunoassay to detect the presence of an analyte fluid. This same sensor may be configured to detect and transmit the results of the assay to the transceiver **202** and on to the database **216**.

I. Temperature Sensing

Materials with various solid-liquid transition temperatures can be placed on or with the wetness sensor **10***a,b* to enable temperature sensing. When the material reaches its melting temperature it will turn to liquid which will activate the sensor **10***a,b*. As describes above, the sensor **10***a,b* then transmits a signal to the transceiver.

Suitable materials include materials, mixtures, and compounds with adjustable solid-liquid transition temperatures depending on the material composition including can be eutectic, peritectic, or pressure-sensitive phase transition materials.

This aspect of the invention may be used to determine when a box, crate, device, or item exceeds a certain temperature. This may be useful for applications that require very careful temperature control such as food storage, organs for transplant storage, and storage of organic or other samples for testing.

J. Moisture Sensing in Materials or Air

A number of desiccants and other hygroscopic materials absorb humidity. For example, some gels, gelatins, acrylates, and other materials readily absorb moisture. Because the sensors **10***a,b* function using very low power, this allows the sensor **10***a,b* to generate a voltage and current even in partially-wetted environments if a conductive path through the hygroscopic material or moisture absorbent material is available.

This is also useful for testing condensation that may accumulate over a period of days. The sensor **10***a,b* may act as a high humidity sensor, an air leakage sensor, in an airtight container, or for many other purposes.

K. Pressure Sensing

A pressure sensor can be created by augmenting the wetness sensor with a small packet of liquid that is adapted to be released when pressure is applied to the packet. This packet may contain salt water and be made of different materials and construction to optimally trigger the sensor when a desired pressure is achieved.

Additionally, this configuration may be used to activate the sensor "upon demand" by simply squeezing the packet manually or with a mechanical device. The release of the liquid allows the sensor **10***a,b* to remain wet for many hours, which prolongs the ability of the sensor **10***a,b* to transmit data to the transceiver **202**. For example, the sensor/liquid-packet combination may be placed on surgical sponges for allowing the packet to be broken just before use. The sensor **10***a,b* on the sponge will transmit data continuously while in use. The sponge may then be placed in a metal container to "silence" the transmission upon removal from the body. Additionally, the liquid may be removed by a second process (either drying, removal, or absorption) thus disabling the sensor **10***a,b*.

L. Hand Hygiene Monitoring

Another useful application of the sensor **10***a,b* is in hand hygiene monitoring. In this example, a sensor **10***a,b* may be placed on the hand, wrist, or finger (like a bandage, wrist strap, or ring). The sensor **10***a,b* will trigger and send a signal every time the hands come in contact with soap or other fluids. This signal is transmitted to transceivers **202** in various locations (soap dispensers, patient bed receivers, central stations) for monitoring compliance with hand hygiene protocols.

The invention has been described above with reference to preferred embodiments. Unless otherwise defined, all technical and scientific terms used herein are intended to have the same meaning as commonly understood in the art to which this invention pertains and at the time of its filing. Although various methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described. However, the skilled should understand that the methods and materials used and described are examples and may not be the only ones suitable for use in the invention.

Accordingly, this invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough, complete, and will fully convey the scope of the invention to those skilled in the art. Therefore, in the specification set forth above there have been disclosed typical preferred embodiments of the invention, and although specific terms are employed, the terms are used in a descriptive sense only and not for purposes of limitation. The invention has been described in some detail, but it will be apparent that various modifications and changes can be made within the spirit and scope of the invention as described in the foregoing specification and the appended claims.

That which is claimed is:

1. A liquid sensor comprising:

a liquid transport layer positionable next to the skin of a wearer and capable of transporting a volume of liquid discharged by the wearer away from the wearer's skin;

a liquid absorbent layer that receives the transported liquid;

a sensor in liquid communication with the liquid absorbent layer, the sensor comprising a substrate having a plurality of electrodes, a circuit, and a transmitter thereon;

the plurality of electrodes being coupled to generate electrical power when in contact with liquid;

the circuit being electrically connected to the electrodes and configured to be activated by the electrical power, detect an electrical parameter of the electrical power, and generate a plurality of data packets indicating a degree of wetness corresponding to the detected electrical parameter, store the electrical power until a pre-determined electrical power value is met, and subsequently release the stored electrical power to the transmitter, wherein successive data packets are separated by a time interval, the time interval being proportional to the time required to reach the pre-determined electrical power;

the transmitter being electrically coupled to the circuit and configured to receive the plurality of data packets and transmit representations of the plurality of data packets as electromagnetic signals.

2. The liquid sensor of claim **1**, wherein each successive data packet is separated by a time interval, the time interval being proportional to the detected electrical parameter.

3. The liquid sensor of claim **1**, wherein a data packet is generated when the electrical power is released.

4. The liquid sensor of claim **1**, wherein the detected electrical parameter is selected from voltage, resistance, current, or a combination thereof.

5. The liquid sensor of claim **1**, wherein the degree of wetness corresponds to an amount of liquid in proximity to the electrodes.

6. The liquid sensor of claim **1**, wherein the substrate is a flexible electrical insulator and includes a generally planar surface and wherein the plurality of electrodes, circuit, and transmitter are arranged in a co-planar relationship along the generally planar surface.

7. The liquid sensor of claim **1**, wherein the substrate is elongated along a lengthwise direction, a first electrode includes a first electrically conductive wire extending along the lengthwise direction and a second electrode includes a second electrically conductive wire extending along the lengthwise direction.

8. The liquid sensor of claim **1**, wherein the liquid sensor is positioned on an undergarment of a user.

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